Strategies & Protections that Have Worked!: **HIPAA & Common Rule**

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Duke University Health System

- Duke University hybrid covered entity
 - Duke Health Enterprise (Affiliated Covered Entity): Health System Schools of Medicine/Nursing/Allied Health
 - Affiliated Organizations • Non-health care University activities are

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- outside of the covered function
- IRB is given responsibility for HIPAA implementation in research

Duke University Health System HIPAA Implementation Features

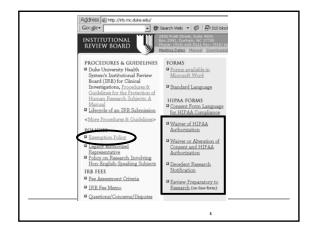
- Combined ICF & Authorization for Research
- Most HIPAA Waivers combined with **Common Rule Waivers**
- IRB Chair signs Data Use Agreements for research
- IRB receives HIPAA notices
 - Review Preparatory to Research
 - Decedent Research

Duke University Health System **HIPAA** Implementation Tools

- IRB Policies
 - Exemption Policy
 - Database Policy
- Web Tools
 - Notice of Reviews Preparatory to Research
 - Disclosure Accounting (ACE provided) (most research activities are uses or with Authorization)

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Policy on Research Databases and Specimen Repositories (Version 04/30.04.) Duke University Health System (DUHS) Institutional Review Board (IRB)

Introduction Databases and specimen repositories (sometimes called registries, banks, or libraries) are used to store data and/or specimeen for future use. When the use is for clinical purposes or quality improvement (QI). IRB approval is not required. However, when the use is for research purposes, the databases/repositories must be approved by the IRE. The databases/repositories must satisfy the

- Handout is still Draft Policy
- Check http://irb.mc.duke.edu for final.

Duke University Health System HIPAA Data Hierarchy

- In Notebook
- Provided by NCHICA Members
- Helps to determine minimum identifier level

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Duke University Health System HIPAA Implementation Headaches

- Non-patients are covered under HIPAA in this schema
 - surveys
 - normal volunteers
- Providing Notice of Privacy Practices

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- Tracking Acknowledgements
- Tracking Disclosures

Duke University Web Resources

- DUHS IRB: http://irb.mc.duke.edu
- NCHICA: <u>www.nchica.org</u>
 AMC & HIPAA conference in June
- NIH: http://privacyruleandresearch.nih.gov/