

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

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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

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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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The screenshot shows the website for the Institutional Review Board at Duke University Health System. The page is organized into two main columns: 'PROCEDURES & GUIDELINES' and 'FORMS'. Under 'PROCEDURES & GUIDELINES', there are links for 'Duke University Health System's Institutional Review Board (IRB) for Clinical Investigations, Procedures & Guidelines for the Protection of Human Research Subjects: A Manual', 'Lifecycle of an IRB Submission', 'Exemption Policy' (circled in red), 'Legacy Institutional Representative', 'Policy on Research Involving Non-English-Speaking Subjects', 'IRB FEES', 'Fee Assessment Criteria', 'IRB Fee Memo', and 'Questions/Concerns/Disputes'. Under 'FORMS', there are links for 'Forms available in Microsoft Word', 'Standard Language', 'HIPAA FORMS', 'Consent Form Language for HIPAA Compliance', 'Waiver of HIPAA Authorization', 'Waiver or Alteration of Consent and HIPAA Authorization', 'Decedent Research Notification', and 'Review Preparatory to Research (on-line form)'. The browser address bar shows 'http://irb.mc.duke.edu/'.

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Duke University Health System Database & Tissue Repository Policy

Policy on Research Databases and Specimen Repositories (Version 04/2004)
 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 specimens 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 IRB. The databases/repositories must satisfy the

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

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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
 - Tracking Acknowledgements
 - Tracking Disclosures
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Duke University Web Resources

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