LSUHSC IRB Presents:

LUNCH & LEARN

DATABASE & REPOSITORY RESEARCH

November 9, 2022

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Agenda

- Definitions
- When IRB Review is Required
- Creating a Database or Repository
- Using Data or Samples from a Database or Repository

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What is a Protected Health Information?

An individual's health information that is created or received by the health care provider related to the provision of health care by a covered entity that identified or could reasonably identify the individual from which it came.

18 Identifiers as defined by HIPAA:

Name	URL Address	Health Plan Number
Street Address	IP Address	Device Identifiers
Dates (MM/DD/YYY)	Social Security Number	Vehicle Identifiers
Phone Number	Account Numbers	Biometric Identifiers
Fax Number	License Numbers	Full Face Photos
Email Address	Medical Record Number	Other Identifying Characteristics

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Types of Data Sets

Identifiable Data Set
- Includes one or more of the 18 HIPAA-defined identifiers

Limited Data Set
- May include dates, age, and/or city, state, zip

Coded Data Set
- PHI is replaced with an arbitrary code where a key exists

De-Identified Data Set
- No identifiers and no codes

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What is a Database?

- A collection of *health information/data*
- Data is *maintained over time*
- *Access* to the data is *controlled*
- *Multiple individuals* may use this information for a *variety of objectives*
- The data may be *identifiable or coded*

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What is a Repository?

- A collection of *biospecimen*
- Biospecimen is *maintained over time*
- *Access* to the biospecimen is *controlled*
- *Multiple individuals* may use the biospecimen for a *variety of objectives*
- The biospecimen may be *identifiable or coded*

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How is a Database/Repository Different from a Chart Review?

- A database and/or repository is a long-term collection and storage of data that may be used by other investigators to study an objective(s) that has yet to be determined

- A chart review can be a long-term or short-term collection and storage of data used by the study team for an objective(s) that has already been determined

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When is IRB Review Required?

✓ When the principal purpose of the database or repository is research

✓ When the data and/or biospecimen will be used by:

- PI and Study Team
- Other Researchers at LSUHSC
- Researchers at other institutions (*requires DUA*)

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Application to Establish a Database or Repository

New Expedited Application

- Even if the data/biospecimen would be de-identified

- The IRB approval is only for the creation of the database or repository

- *HRP-2603 Guidance on Research Databases and Repositories contains example protocols*

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Application to Use Data or Samples from a Database or Repository

The IRB wants formal documentation of all projects taking place using data and/or biospecimen from a research database or repository, even if the information is de-identified.

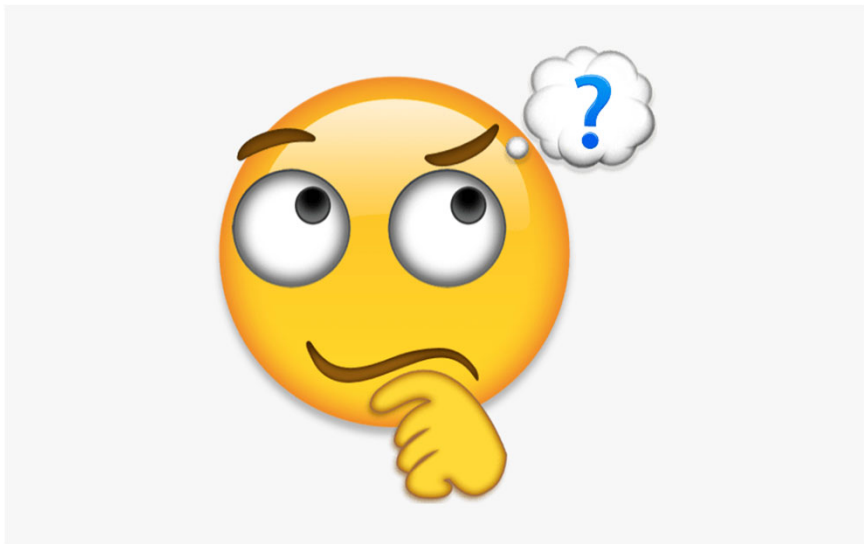| If data/specimen are identifiable or coded	If data/specimen are completely de-identified
• Exempt, if identifiers/code will be destroyed • Expedited, if identifiers/code will be kept	• Non-Human Subjects Research Determination

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Save the Date!

Date	Time	Topic
12/07/2022	12:00PM	Reportable New Information
01/11/2022	12:00PM	Emergency Preparedness in Research
02/01/2022	12:00PM	Informed Consents & HIPAA Authorization
03/01/2022	12:00PM	Expanded Access Use of a Test Article

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Resources

- **IRB Website:** **https://www.lsuhsc.edu/administration/academic/ors/irb/**
- **Database/Repository Guidance (HRP-2603):**
  https://www.lsuhsc.edu/administration/academic/ors/irb/education_guidance_instructions.aspx
- **Consent Templates:**
  https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx

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