Database & Repository Research

November 9, 2022

Agenda

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

<table>
<thead>
<tr>
<th>Name</th>
<th>URL Address</th>
<th>Health Plan Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>IP Address</td>
<td>Device Identifiers</td>
</tr>
<tr>
<td>Dates (MM/DD/YYYY)</td>
<td>Social Security Number</td>
<td>Vehicle Identifiers</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Account Numbers</td>
<td>Biometric Identifiers</td>
</tr>
<tr>
<td>Fax Number</td>
<td>License Numbers</td>
<td>Full Face Photos</td>
</tr>
<tr>
<td>Email Address</td>
<td>Medical Record Number</td>
<td>Other Identifying Characteristics</td>
</tr>
</tbody>
</table>

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
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*

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*
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.

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*)
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

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.*

<table>
<thead>
<tr>
<th>If data/specimen are identifiable or coded</th>
<th>If data/specimen are completely de-identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Exempt, if identifiers/code will be destroyed</td>
<td>• Non-Human Subjects Research Determination</td>
</tr>
<tr>
<td>• Expedited, if identifiers/code will be kept</td>
<td></td>
</tr>
</tbody>
</table>
### Save the Date!

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/07/2022</td>
<td>12:00PM</td>
<td>Reportable New Information</td>
</tr>
<tr>
<td>01/11/2022</td>
<td>12:00PM</td>
<td>Emergency Preparedness in Research</td>
</tr>
<tr>
<td>02/01/2022</td>
<td>12:00PM</td>
<td>Informed Consents &amp; HIPAA Authorization</td>
</tr>
<tr>
<td>03/01/2022</td>
<td>12:00PM</td>
<td>Expanded Access Use of a Test Article</td>
</tr>
</tbody>
</table>
Resources

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