<table>
<thead>
<tr>
<th>Start Here</th>
<th>Does the study involve Protected Health Information?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>The Privacy Rule does not apply</td>
</tr>
<tr>
<td>Yes</td>
<td>Subject Authorization obtained?</td>
</tr>
<tr>
<td>No</td>
<td>PHI without Authorization</td>
</tr>
<tr>
<td>Yes</td>
<td>Data Type?</td>
</tr>
</tbody>
</table>

### PHI with Authorization
- **Required Forms**
  - IRB Application
  - Use HIPAA Subject Authorization Template
- **Representations**
  - Solely for Research
  - Necessary for Research
  - Documentation of death, if required

### Decedents’ Research
- **Application for Decedent’s Research**

### Preparatory Research
- **Preparatory to Research Certification**
  - Necessary for protocol
  - Necessary for Research
  - Data may be copied from 25 records
  - From each record, investigators may copy no more than what is allowed in a Limited Data Set

### Waiver Requested
- **IRB Application**
- **HIPAA Waiver of Subject Authorization form**
  - Research can’t be conducted without waiver
  - Research can’t be conducted without PHI
  - Assurance of no more than minimal risk

### Limited Data Set
- **IRB Application**
- **Execute Limited Data Set Agreement**
  - (template available)
  - Representations:
    - Exclusion of 16 identifiers

### De-identified
- **IRB Application**
  - Representations:
    - Exclusion of 18 identifiers

### Minimum Necessary Standard
- Checkmark

### Accounting of Disclosures
- Checkmark

### Other Requirements
- Business Associate Agreement required for disclosures (i.e., with sponsors)
- Business Associate Agreement required for Disclosures, if applicable
- All Recipients must sign a Data Use Agreement for use or disclosures
- Request for Re-identification key

*Adapted from Loma Linda University*