Objectives of our Multi-stakeholder Work:

- Discuss the risk of re-identification and determine protective mechanisms
  1. Achieve clear definitions of identifiable data, anonymized data, anonymous data, de-identified data, and re-identified data.

- Provide guidance in two areas:
  2. Retrospective consent: Interpret the limitations imposed by language in existing informed consent forms (ICF’s) upon data-sharing.
     - Silent, narrow sharing, broad sharing or conflicting language found in existing forms
  3. Prospective consent: Develop ICF language for patient-level data-sharing acceptable to IRBs and patients groups.
# Suggested Definitions for ICFs - Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>personally identifiable data</td>
<td>information that directly or indirectly identifies you (e.g. name, SSN, address, telephone number, email address)</td>
</tr>
<tr>
<td>coded data</td>
<td>study participant data and samples for which a code is given to replace a person’s name or other specific information.</td>
</tr>
<tr>
<td>de-identified data</td>
<td>data modified to remove the presence of personally identifying information</td>
</tr>
<tr>
<td>your data</td>
<td>your personal and medical data collected during the study, which may be coded or de-identified</td>
</tr>
</tbody>
</table>

![Diagram](image-url)

- **Study site**: coded data
- **Sponsor**: de-identified data
- **External researcher**
Proposed ICF Language for Data Sharing

Key Sections

• What information about me will be used in the study?
• Who may see, use and share your personal and health information?
• How will my information be used?
• How may my data be used for additional research?
• What other information is shared?
• Do I have to participate?
• Can I change my mind?

NOTE: sharing is linked to participation in the study and the form takes an “inform” approach