Reasonable Person Standard meets Social License: consent of the people, by the people, for the people

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Disclosures

• I am Vice President for Policy and Ethics and have stock options at PatientsLikeMe.

• I do not plan on discussing unlabeled/investigational uses of a commercial product.
46.116(a)(4) New Subsection

- Requires that subjects be provided with the information that a “reasonable person” (undefined) would want to have.
- Responsibility remains for the investigator to:
  - Provide more information when requested by subjects
  - Make sufficient time and opportunity to discuss the research
  - Answer questions to improve a subject’s understanding
- For certain types of research (such as, research for which there is reason to believe some subjects will find the research controversial or objectionable), a robust description of the research will be required to meet this reasonable person standard.
<table>
<thead>
<tr>
<th>Reasonable person or reasonable people</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to the social license concept</td>
</tr>
<tr>
<td>Key elements for earning social license</td>
</tr>
<tr>
<td>Reasonable people standard through lens of social license</td>
</tr>
<tr>
<td>Consent of the people, for the people, by the people</td>
</tr>
</tbody>
</table>
Reasonable Person or Reasonable People

Reasonable Person Standard

What would a *hypothetical* reasonable person do, need, or want in the same or similar circumstances?

- Idiosyncratic and inconsistent
- Bias towards homogeneity
- Imposes one ‘idealized’ person’s values on others
- Controversial or objectionable issues less obvious

Reasonable People Standard

What would *real* reasonable people do, need, or want in the same or similar circumstances?

- Identifies values/interests that more accurately represent study cohort
- Opportunity to judge community attributes that matter
- Issues that require more robust material more likely to be obvious
Social License to Operate (SLO) arose from the mining industry.

SLO is broadly defined as:
- the extent to which an entity is constrained to meet societal expectations and avoid activities that people and their communities deem unacceptable.

SLO has three essential preconditions:
- Legitimacy
- Credibility
- Trust
Key elements for earning social license

**Transparency / Intent**
- Openness to divergent views
- Trustworthiness based on shared information

**Fairness / Integrity**
- Ensure “smaller” voices are included and heard
- Authenticity in relationship building – be human

**Informed consent**
- Builds dialogue
- Relies on both transparency and fairness
Reasonable people standard ‘PLUS’ through lens of social license

Let reasonable people determine whether the informed consent meets their standard

• **Inclusiveness** *(increases legitimacy)*
  – People who represent the intended population need to participate in the study design process – including content of the key information in the informed consent

• **Evaluation of materials** *(establishes credibility)*
  – A representative sample of potential study participants are best suited to offer opinions and perspectives on the information provided in the informed consent
  – Opportunity to illuminate whether certain people will need more robust description of the research

• **Consistency of evaluation** *(builds trust)*
  – People for whom the study matters more likely to bring relevant issues to table
  – For people considering the study it matters that others like them were included in all phases of design, material development and evaluation
Consent of the people, by the people, for the people

• Earn social license from a representative group of real people about what they need and want to make an informed decision about a research study.

• Seek to understand the similarities and differences about what matters most to participants, researchers and IRBs to foster effective and meaningful outcomes.

• Be wary of a non-quantifiable standard that purports to bring objectivity to informed consent – it may actually introduce new vulnerabilities.

• Continue to learn from the experiences of real study participants about the informed consent process.

• Most importantly share what you learn with participants, researchers and the IRB community.
Considerations for the IRB Community

• Put the interests of *reasonable real people first* - this is always a defensible position.

• **Be open** to interpreting the requirements of 46.116(a)(4) through the lens of the social license to support an informed consent process that is built upon transparency, intent, fairness and integrity.

• Let investigators know that you expect:
  – To review study designs and materials that have been developed in partnership with potential participants, **AND**
  – Evidence that the materials have been reviewed, evaluated and determined to meet the standard of what a representative group of reasonable real people need and want to make an informed decision
Reference materials


Thank you!

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