Informed Consent: Nuts and Bolts

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Disclaimer

The views expressed in this talk are my own. They do not represent the position or policy of the NIH, DHHS, or US government.
Summary

• Consent is a process not a form
• The informed consent process is only one opportunity among many to convey respect to potential research subjects.
Best Practices

• Consent Form
  • Style
  • Format
• Promoting Understanding
Style

- Short sentences
- Short words
- Simplify text
- State main ideas clearly
- One idea per paragraph
- Clearly state purpose

Sources: Taylor (1999); Johns Hopkins Medicine (2022)
Style

• Present clear sequence of events/procedures
• Avoid irrelevant information
• Avoid legal jargon
• Write in conversational style
• Write in active voice

Source: Taylor (1999); Johns Hopkins Medicine (2022)
Style

• Be consistent with words and terminology
• Define technical or difficult words
• Know your audience
• Have forms reviewed by patient
• Use computer tools to assess readability

Source: Taylor (1999); Johns Hopkins Medicine (2022)
Format

• Use a readable type style (sans serif)
• Use 12-14 point type for text, 16-18 bold type for headings
• Use upper case and lower case for text
• Double spaced
• Space between sections
• Have 50/50 blend of white space and text

Source: Taylor (1999); Johns Hopkins Medicine (2022)
Format

• Use heading and advance organizers to introduce useful informational components (e.g. questions or declarative statements)
• Question/answer format
• Use lists whenever possible
• Use tables or boxes

Source: Taylor (1999); Johns Hopkins Medicine (2022)
Understanding

• Understanding is improved when patients or subjects must *verbalize information*, and
• Understanding is improved by administering quizzes and correcting inaccurate responses
<table>
<thead>
<tr>
<th>Topic area</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>“If you were going to tell a friend what this study was about, what would you say?”</td>
</tr>
<tr>
<td>Procedures</td>
<td>“What are the main things you will do or will happen to you while you are in this study?”</td>
</tr>
<tr>
<td>Randomization</td>
<td>“Does everyone in this study have to do the same thing?”</td>
</tr>
<tr>
<td></td>
<td>“Tell me in your own words how the researchers will decide whether you get the [intervention] or the [usual care]?”</td>
</tr>
<tr>
<td>Risks</td>
<td>“What are the risks, or bad things that might happen to you if or when you join this study?”</td>
</tr>
<tr>
<td>Benefits</td>
<td>“What are the benefits, or good things that might happen to you if or when you join this study?”</td>
</tr>
<tr>
<td>Voluntariness</td>
<td>“What will happen if you decide you don’t want to be in the study?”</td>
</tr>
<tr>
<td></td>
<td>“What can happen if you decide to be in the study but later change your mind?”</td>
</tr>
</tbody>
</table>

Source: Kass et al (2014)
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