Developing Better Consent Forms

Clear Communication Principles for Written Consent
September 19, 2019
University of Maryland, Baltimore
HS/HSL Consent Form Review Service

1. HS/HSL started a consent form review service in 2011.
2. The service aims to improve readability level.
   • The average U.S. adult reads at an 8th grade level.
   • Target level for UMB consent forms = 8th grade.
   • Target level for the VA MD Health Care System (VAMHCS) = 7th grade.
HS/HSL Consent Form Review Service

1. To date, we have reviewed 208 consent forms.
2. Average grade level received: 11.0 / returned: 8.4.

CF review submissions 2013-present

<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>10</td>
</tr>
<tr>
<td>UMB Dentistry</td>
<td>8</td>
</tr>
<tr>
<td>UMB Graduate Studies</td>
<td>1</td>
</tr>
<tr>
<td>UMB Medicine</td>
<td>157</td>
</tr>
<tr>
<td>UMB Nursing</td>
<td>7</td>
</tr>
<tr>
<td>UMB Pharmacy</td>
<td>14</td>
</tr>
<tr>
<td>UMB Social Work</td>
<td>10</td>
</tr>
<tr>
<td>VA Hospital</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>208</td>
</tr>
</tbody>
</table>

Who is submitting?

- Other
- UMB Dentistry
- UMB Graduate Studies
- UMB Medicine
- UMB Nursing
- UMB Pharmacy
- UMB Social Work
- VA Hospital

75%
Consent Form Readability: Why Does It Matter?

1. Maintain ethical principles -
   - *The Belmont Report*
     - Respect of Persons - Informed Consent
     - Beneficence - Assessment of Risks and Benefits
     - Justice - Selection of Subjects

2. Conform to Federal regulations: the “Common Rule” (CFR 45 part 46)

3. Promote and maintain our institutional reputation

4. Promote trust in the research enterprise
Issues with Submissions & How to Address Them

1. Formal, bureaucratic writing style
2. Templates and template language
3. Technical terminology and scientific jargon
4. Reading level and readability
5. Information design and formatting
6. Tables and figures
Formal, Bureaucratic Writing Style

2. Analyze situation and audience.
3. Use plain language to create a clear, direct, and respectful tone.
Templates and Template Language

1. Use judgement; consider context.
2. Not all template language needs to be included verbatim.

   A. State the following in this section –
      - “Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you may withdraw from the study at any time, for any reason, without prejudice to your rights and without having to explain your reason.”

   B. If applicable please add the following –
      - “You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.”

3. When transferring content, avoid unnecessary repetition, and consider the order and flow of information.
Technical Terminology & Scientific Jargon

1. Do not copy text from the research protocol and paste it into the informed consent template.
2. Use terms consistently to avoid confusion.
3. Define unfamiliar terms as they are introduced.
4. Avoid research terms:

<table>
<thead>
<tr>
<th>Research terms:</th>
<th>subject</th>
<th>phase I clinical trial</th>
<th>principal investigator</th>
<th>study arms</th>
<th>administer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay terms:</td>
<td>participant</td>
<td>research study</td>
<td>study doctor</td>
<td>study groups</td>
<td>give</td>
</tr>
</tbody>
</table>

5. Use the lay term only. Don’t use a technical term followed by a lay term in parentheses: *dysphagia (difficulty swallowing)*, *edema (swelling) pruritus (itching)*.
Jargon Continued...

1. Avoid using mathematical symbols: $\geq 50$, $>1\%$, or $\sim 50$.
2. Use household measures for blood samples: tablespoon, teaspoon, cup, pint.
3. Use acronyms.
4. Check consumer health websites.
5. Don’t “teach” a list of technical terms.
6. Consider what the participant *needs to know* for informed consent.
1. Readability formulas can alert us to problems with the writing.

2. In MS Word, select File > Options > Proofing > Show readability statistics.
   - 7\textsuperscript{th}-8\textsuperscript{th} grade reading level,
   - Reading ease score above 50, and
   - Under 30\% passive sentences.
Reading Level and Readability

MS Word readability statistics before and after HS/HSL’s consent form review service
Plain Language Readability Guidelines

1. Keep sentences short: 15-20 words for a general audience, 8-15 for less skilled readers.
2. Use the active voice.
3. Prefer simple sentences: Subject comes first and verb follows closely.
4. Avoid filler words and empty phrases.
5. Aim for fewer than 3 syllables, when possible.
6. Avoid legalistic phrases: and/or, includes but is not limited to.
7. Avoid Latin elements: e.g., i.e., Nota Bene.
Information Design and Formatting

1. Avoid large blocks of undifferentiated text.
2. Do not bullet point the entire document.
3. Use formatting to emphasize content and help your reader navigate the text.
4. Avoid full justification of text.
5. Use a 12-point serif font and 1-inch margins.
Tables and Figures

1. Should convey information in a clear and simple manner.
2. Avoid examples that are vague, confusing, or visually busy.
Your implanted Boston Scientific ICD or CRT-D (Figure 1) is approved for commercial use in the United States. Your doctor’s use of the device to treat your medical condition is the standard of care at your hospital. The implant procedure is not a part of this study.

Figure 1: Example of the ICD and CRT-D implanted device that has the heart failure sensors
Unhelpful Example 2

Figure 1 Study design

Legend:
- Red box: Standard Operating Procedure
- Yellow box: FUS Frame, Navigation Fiducials, IVs placed
- Pink box: MRI
- Gray box: MRI review/Target planning
- Blue box and lines: Low power FUS pulses to Tumor-region Target
- Purple box: Microbubble infusion (Definity or equiv.)

MRI-FUS Center

- Patient arrives at MRI-FUS center
- Patient placed in MRgFUS scanner
- Patient removed from MRgFUS scanner

Acoustic Emissions Safety Monitoring

Patient transported directly to OR

[Goal: 1-2 hrs] [Goal: 15min]
Tables and Figures, cont.
Unhelpful Example 2 (grayscale version)

Figure 1 Study design
### Figure 3 Expected side effects from MRI contrast agent

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Frequency</th>
<th>Severity</th>
<th>Long Term Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death and other serious adverse reaction</td>
<td>Rare (0-1%)</td>
<td>Mild</td>
<td>X</td>
</tr>
<tr>
<td>Headache</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Nausea</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Localized injection site coldness</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Dizziness &amp; hives</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

### Figure 4 Expected side effects from Definity® ultrasound contrast agent

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Frequency</th>
<th>Severity</th>
<th>Long Term Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pulmonary arrest</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Anaphylactic like reaction</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Loss of consciousness</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Symptomatic arrhythmias</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hypotension</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Convulsions</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Headache</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Back and renal pain</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Flushing</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Thank You

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