Consent Form Readability

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Consent Form Length

• 20 – 30 page consent forms not uncommon
• Studies suggest shorter/simpler is better
• Consent forms should be shorter and easy to understand
Consent Form Length

• Subjects have the right to understand the study.
• Some subjects actually read the consent form.
Elements of Consent

- Research
- Purpose
- Duration
- Procedures
- Experimental Procedures
- Risks
- Benefits
- Alternatives
- Confidentiality
- Research Related Injury
- Contact Info
- Voluntary
- Unforeseeable Risk
- Termination w/o Consent
- Cost
- Early Termination
- New Findings
- Number of Subjects
Elements of Consent

• Common Rule 45 CFR 46.116: 8 + 6 = 14+
• Jefferson RQ-1 reviewer form: 26
• Wyeth (RIP): 27

• Not suggesting that we don’t include all elements
Elements of Consent

• A 1 page consent is (sort of) possible
  • Contained all the elements

• Few procedures
• Separate HIPAA
• Formatting
How to Simplify

When Writing/Reviewing Consent:

- Change your mindset (Researcher to Teacher)
- Protocol is for Inv. – Consent is for Subjects
- Copy + paste from protocol may not be appropriate
Procedures

• Procedure A: Visit 1
• Procedure B: Visit 1 and 2
• Procedure C: Visit 1, 2 and 3
## Procedures

<table>
<thead>
<tr>
<th></th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure A</strong></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Procedure B</strong></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Procedure C</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
How to Simplify

• Concisely address each element
• Use short sentences
• Avoid technical terms
• Do not repeat information
• Use conversational language
Reading Level

• 6\textsuperscript{th} to 8\textsuperscript{th} Grade?
• Microsoft Word – Flesch-Kincaid Grade Level
• File $\rightarrow$ Options $\rightarrow$ Proofing $\rightarrow$ Show Readability Statistics (Shown After a Spell Check)
# Readability Statistics

**Counts**
- Words: 902
- Characters: 4517
- Paragraphs: 48
- Sentences: 54

**Averages**
- Sentences per Paragraph: 2.3
- Words per Sentence: 15.0
- Characters per Word: 4.7

**Readability**
- Passive Sentences: 48%
- Flesch Reading Ease: 51.8
- Flesch-Kincaid Grade Level: 9.7
Reading Level

• Just use conversational language
The Jefferson Bible
The Declaration of Independence

• ORIGINAL: When in the Course of human events, it becomes necessary for one people to dissolve the political bands which have connected them with another, and to assume among the powers of the earth, the separate and equal station to which the Laws of Nature and of Nature's God entitle them, a decent respect to the opinions of mankind requires that they should declare the causes which impel them to the separation. 15.1

• REVISED: The 13 United States of America are breaking ties with Britain. We are doing this to create a separate and equal government. We believe we have a right to do this, but also believe you have the right to know why. 6.1

The Revised Declaration of Independence © Copyright 2014 Patrick Herbison
What Can You Do
(Writers/Reviewers)

• Industry Sponsored Studies

• Investigator Initiated

• When reviewing consent forms, don’t take the stance that “no one is going to read this anyway”. If something is hard to understand, ask for a revision.
What Can I DO?

• Revise the Jefferson Consent Template
Questions?