

Consent Form Readability

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IRB Member Continuing Education

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

	Visit 1	Visit 2	Visit 3
Procedure A	X		
Procedure B	X	X	
Procedure C	X	X	X

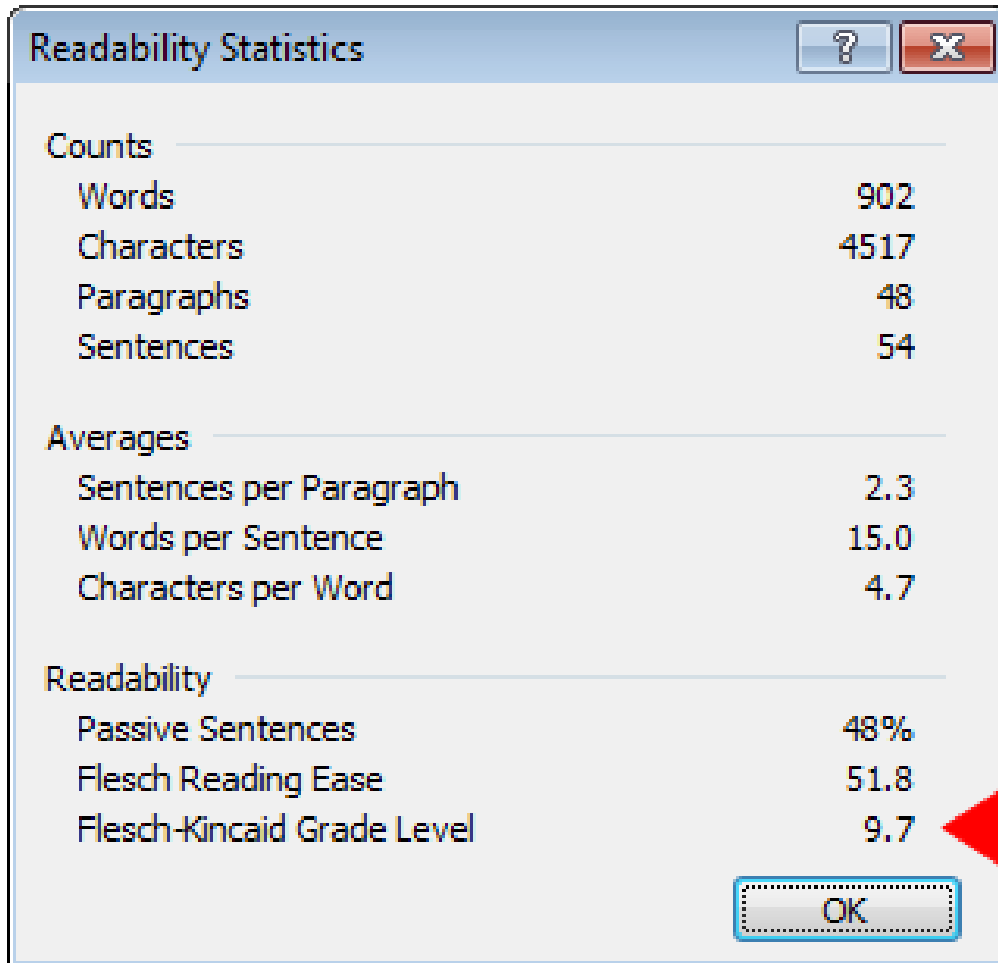
How to Simplify

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

Reading Level

- 6th to 8th Grade?
- Microsoft Word – Flesch-Kincaid Grade Level
- File → Options → Proofing → 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

OK



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?