

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.

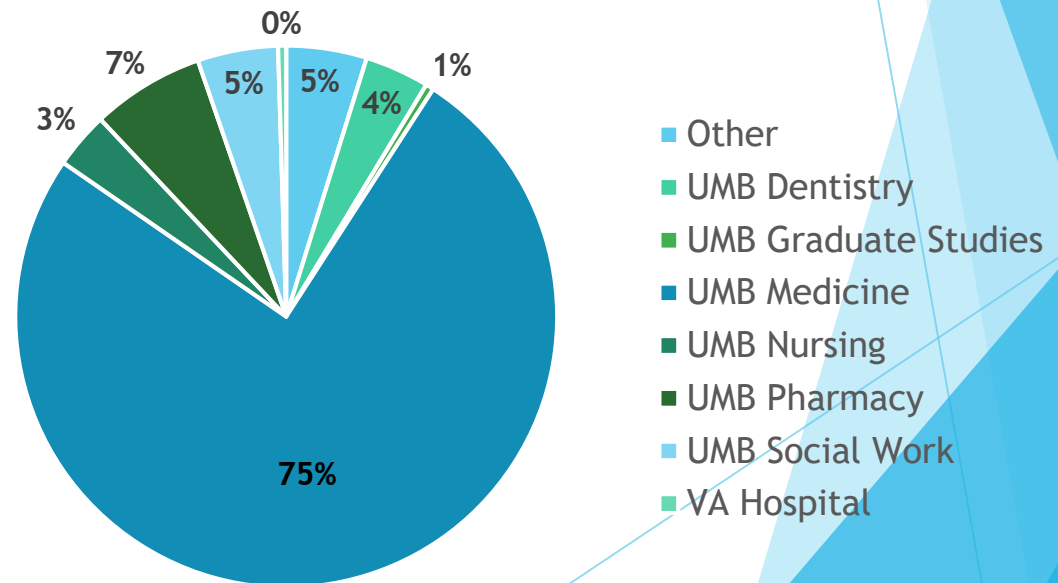
HS/HSL Consent Form Review Service

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

CF review submissions 2013-present

Affiliation	Submissions
Other	10
UMB Dentistry	8
UMB Graduate Studies	1
UMB Medicine	157
UMB Nursing	7
UMB Pharmacy	14
UMB Social Work	10
VA Hospital	1
Total	208

Who is submitting?



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

1. Consider tone and register.
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.

State the following in this section –

- A.
- “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

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:

Research terms:	subject	phase I clinical trial	principal investigator	study arms	administer
Lay terms:	participant	research study	study doctor	study groups	give

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: ≥ 50 , $> 1\%$, or ~ 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.

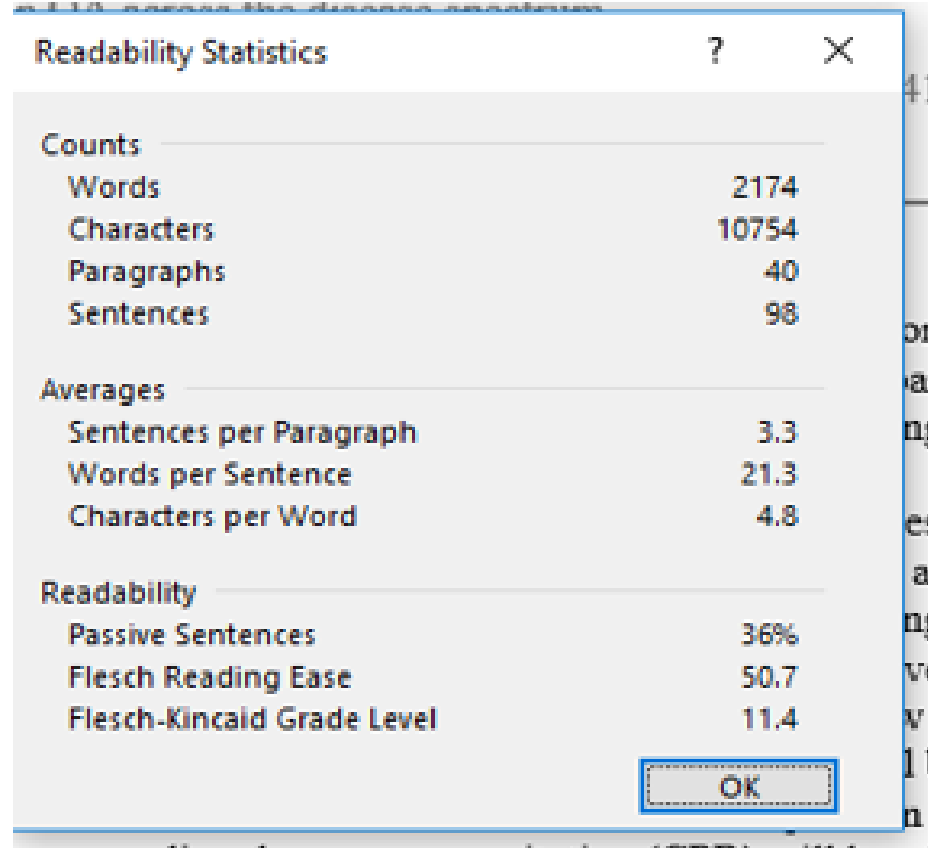
Reading Level and Readability

1. Readability formulas can alert us to problems with the writing.
2. In MS Word, select **File > Options > Proofing > Show readability statistics.**
 - 7th-8th 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

Before: 11.4



The screenshot shows the 'Readability Statistics' dialog box in MS Word. The dialog box is titled 'Readability Statistics' and has a question mark icon and a close button (X). It displays the following statistics:

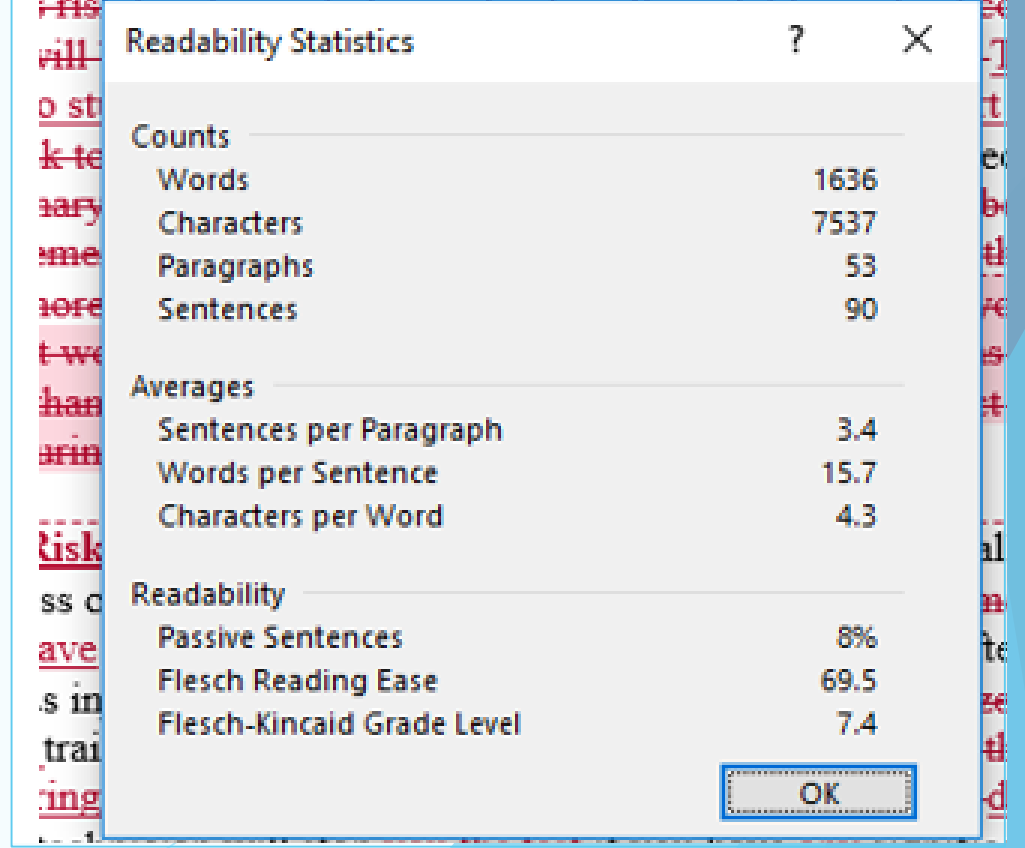
Counts	
Words	2174
Characters	10754
Paragraphs	40
Sentences	98

Averages	
Sentences per Paragraph	3.3
Words per Sentence	21.3
Characters per Word	4.8

Readability	
Passive Sentences	36%
Flesch Reading Ease	50.7
Flesch-Kincaid Grade Level	11.4

An 'OK' button is visible at the bottom right of the dialog box.

After: 7.4



The screenshot shows the 'Readability Statistics' dialog box in MS Word after the review service. The dialog box is titled 'Readability Statistics' and has a question mark icon and a close button (X). It displays the following statistics:

Counts	
Words	1636
Characters	7537
Paragraphs	53
Sentences	90

Averages	
Sentences per Paragraph	3.4
Words per Sentence	15.7
Characters per Word	4.3

Readability	
Passive Sentences	8%
Flesch Reading Ease	69.5
Flesch-Kincaid Grade Level	7.4

An 'OK' button is visible at the bottom right of the dialog box.

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.

Tables and Figures, cont.

Unhelpful Example 1

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









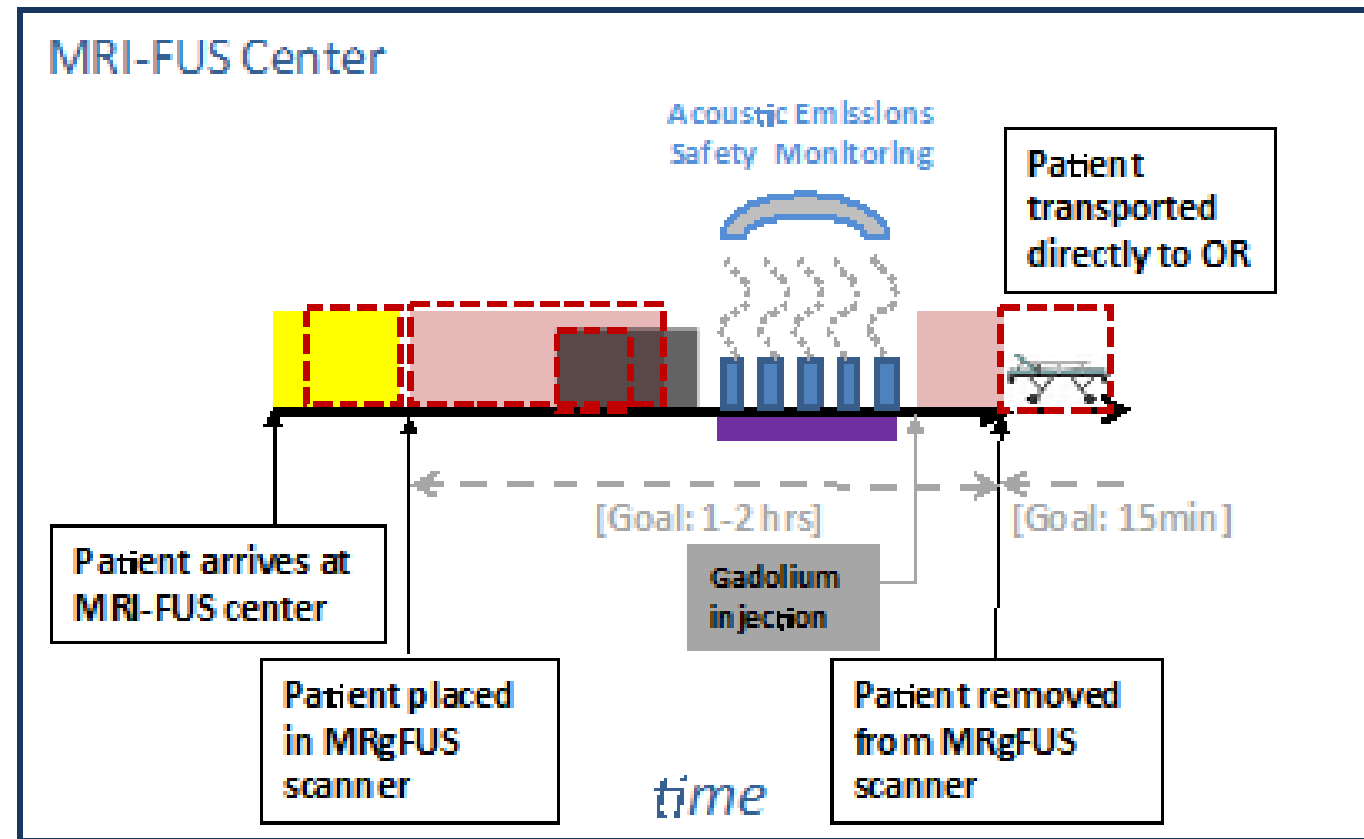
Tables and Figures, cont.

Unhelpful Example 2

Figure 1 Study design

Legend:

-  Standard Operating Procedure
-  FUS Frame, Navigation Fiducials, IVs placed
-  MRI
-  MRI review/
Target planning
-  Low power FUS pulses to Tumor-region Target
-  Microbubble infusion (Definity or equiv.)









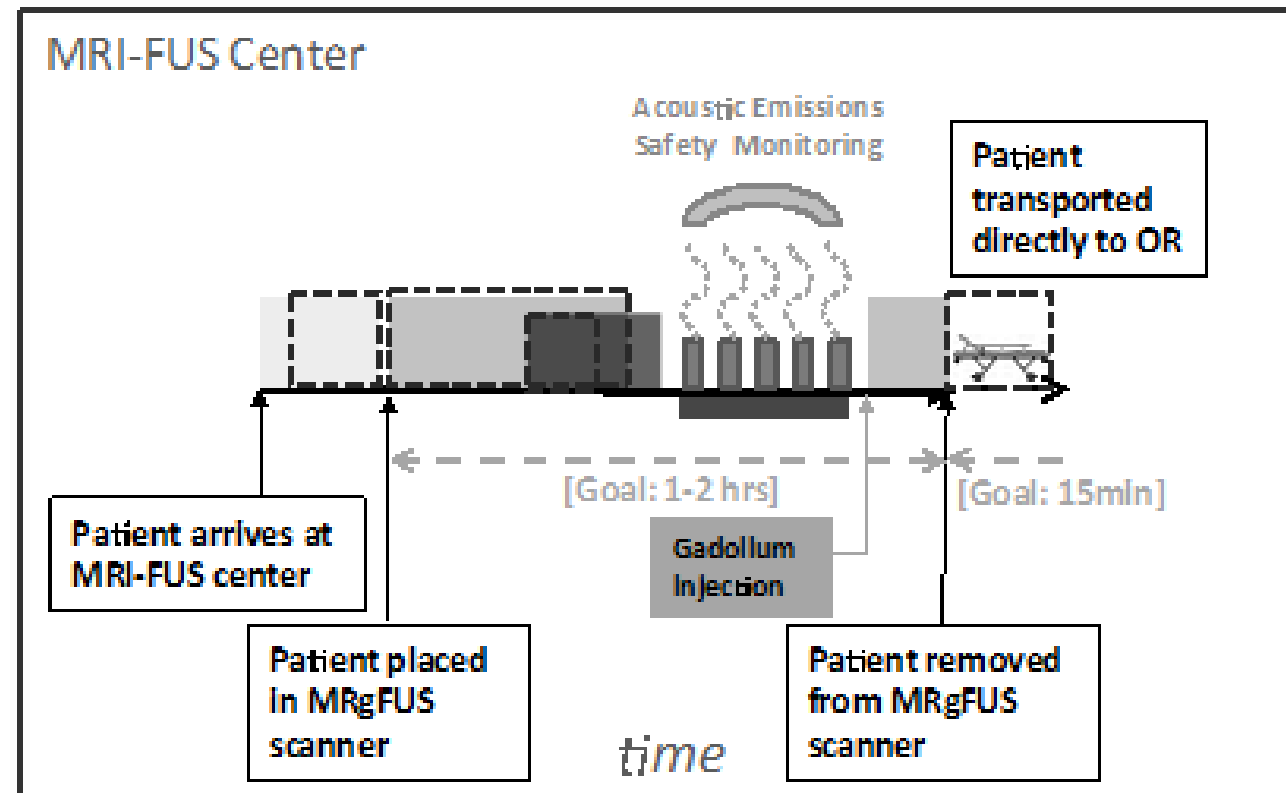
Tables and Figures, cont.

Unhelpful Example 2 (grayscale version)

Figure 1 Study design

Legend:

-  Standard Operating Procedure
-  FUS Frame, Navigation Fiducials, IVs placed
-  MRI
-  MRI review/ Target planning
-  Low power FUS pulses to Tumor-region Target
-  Microbubble infusion (Definity or equiv.)



Tables and Figures, cont.

Unhelpful Example 3

Figure 3 Expected side effects from MRI contrast agent

Side Effect	Frequency				Severity			Long Term Impact	
	Very Likely (30-100%)	Likely (10-30%)	Less Likely (1-10%)	Rare (0-1%)	Mild	Moderate	Severe	Temporary	Permanent
Death and other serious adverse reaction				X			X		X
Headache			X		X			X	
Nausea			X		X			X	
Localized injection site coldness			X		X			X	
Dizziness & hives			X		X			X	

Figure 4 Expected side effects from Definity® ultrasound contrast agent

Side Effect	Frequency				Severity			Long Term Impact	
	Very Likely (30-100%)	Likely (10-30%)	Less Likely (1-10%)	Rare (0-1%)	Mild	Moderate	Severe	Temporary	Permanent
Death				X			X		X
Cardiac arrest				X			X		X
Pulmonary arrest				X			X		X
Anaphylactic like reaction				X		X		X	
Loss of consciousness				X		X		X	
Symptomatic arrhythmias				X		X		X	
Hypotension				X		X		X	
Convulsions				X		X		X	
Headache			X		X			X	
Back and renal pain				X	X			X	
Flushing					X			X	

Thank You

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