

# Tips on Modifying and Writing Informed Consents

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## Purpose of an IC

1. To describe the research study clearly and concisely, so that the potential subject:
  - knows what s/he will have to do as a participant
  - can decide whether s/he wishes to be part of the study
2. To comply with Federal Regulations

## Health Literacy

The ability to obtain, process, and understand basic information and services needed to make appropriate health decisions.

Assessment: The Newest Vital Sign  
(NVS)

## Newest Vital Sign (NVS)

1. If you eat the entire container, how many calories will you eat?

## Newest Vital Sign (NVS)

2. If you are allowed to eat 60 g of carbohydrates as a snack, how much ice cream could you have?

## Newest Vital Sign (NVS)

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?

## Newest Vital Sign (NVS)

4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?

## Newest Vital Sign (NVS)

Pretend you are allergic to the following: Penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?

## Newest Vital Sign (NVS)

6. Why not?

## NVS Answers

1. 1,000
2. 2 servings or half the container or 1 cup (or any amount up to 1 C)
3. 33
4. 10%
5. No
6. Because it has peanut oil in it

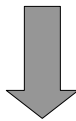
## NVS Scoring

# of questions answered correctly	Health Literacy Level
$\geq 3$	Adequate
2	Possible low
$\leq 1$	Low

*To be considered adequate, just 50% correct*

## Health Literacy

- National estimates indicate 50% of adults have inadequate health literacy



- Half your patients can't understand the study or the consent

## The NVS

- Takes about 3 minutes to give
- Agrees with national estimates of 50% health literacy level in adults
- Helps you figure out the best way to communicate with the subject

Weiss et al., Ann Fam Med 2005; 3: 514

### Guiding Principle:

Make it easy for your audience

1. Minimize amount of reading
2. Present info for maximum clarity
3. Check for understanding

## Visual Components

- Bigger is better
- Written information we are given to read (and posters):

### Serif Fonts

Times New Roman

Bookman Old Style

Perpetua

## Visual Components

- Bigger is better
- Information on slides or posted on walls:

### Sans Serif Fonts

Arial

Comic Sans MS

Lucida Sans



## Visual Components

Printed matter

### Serif Fonts

Times New Roman  
Bookman Old Style  
Perpetua

Posted  
material

### Sans Serif Fonts

Arial  
Comic Sans MS  
Lucida Sans

## Tools

1. Simple words and phrases
2. Layman's Explanation of Terms
3. Grade level readability comparison  
(Flesch-Kincaid reading level)

## Tool Examples

### 1. Simple words and phrases

<http://plainlanguage.gov/howto/wordsuggestions/simplewords>

<b>INSTEAD OF</b>	<b>TRY</b>
Anticipate	Expect
Discontinue	Drop, stop
In the event of	If
Participate	Take part
Terminate	End, stop

## Tool Examples

### 2. Layman's Explanation of Terms

<b>Condition/Disease /Treatment</b>	<b>Explanation</b>
Adverse Events	Side effects
Edema	Swelling in body tissues
Explant	Remove from a position within or on the body
Jaundice	Yellow-appearing skin and whites of the eyes

Grade level readability comparison  
(Flesch-Kincaid reading level)

In WORD:

Tools Menu

Options

Spelling & Grammar

Check grammar with spelling

Show readability statistics

*Our model consent: 10.7*

Readability Level: 6<sup>th</sup> Grade

“Taking part in this study is your choice. If you decide not to take part, this will not harm your relations with your doctors or with the University.”

N Engl J Med 2003; 348: 721-6.

## Readability Level: College

“You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University.”

N Engl J Med 2003; 348: 721

## What's Key to Readability Level?

Flesch-Kincaid Grade Level Formula:

$$(.39 \times ASL) + (11.8 \times ASW) - 15.59$$

ASL = average sentence length  
(# of words / # of sentences)

ASW = average # of syllables per word  
(# of syllables / # of words)

Guiding Principle:  
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As I work on my consent, I can hear Dr. Moore say:

1. Simplify your terms
2. Edit! Too much text!
3. Look for Clarity!
4. Spell check!
5. Proofread
6. All of the above!!!!

 Remember: We Can Help! 

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