

## HOW TO WRITE A CONSENT DOCUMENT THAT YOUR SUBJECTS CAN UNDERSTAND

*The goal of this issue of HRPP Topics is to help you to write an informed consent document that your subjects can understand. The consent document for adults should be written at an 8<sup>th</sup> grade reading level. To give you an example of how that might read, this article has been written so that the Flesch-Kincaid Grade Level score is “8<sup>th</sup> grade.” (See below for how to check your MS Word documents for reading level.)*


The written consent document provides subjects with information about your study and what they are being asked to do. Once they have that information, they can decide if they want to participate. Giving your subjects a “choice” is based on the rule of “respect for persons” that is stated in the Belmont Report. It says that subjects must be given the chance to choose what will or will not happen to them. If they can’t understand the consent document, they can’t make an informed choice about whether to participate in your study.

Here are some suggestions for writing Consent Documents that read at an 8th grade level:

- Use text fonts and font sizes that are easy to read. Here are some suggestions:

This is a good suggestion	Times New Roman - 12 pt
This is a good suggestion	Arial - 11 pt
This is a good suggestion	Veranda – 10 pt
This is a good suggestion	Tahoma – 10 pt
- Use simple words.
- Keep sentences short.
- When possible, use words with 2 syllables or less.
- Do not use run-on sentences.
- Whenever possible, do not use scientific and/or medical words (instead of “you may experience vertigo,” say “you may feel dizzy”). If you must use the medical or scientific word, provide the lay term in parenthesis.
- Change all passive voice sentences to active voice (instead of “a form will need to be filled out,” say “you will fill out a form”).
- Keep the consent document to a reasonable length. If procedures are complicated and there are different parts to the study, think about having a separate document for each part.
- Be specific about procedures that the subject will really experience. Subjects generally care more about how many needle sticks they will have, the types of questions they will be asked, and how many hours the study will take than the real names of the tests or the names of the questionnaires.
- When you write about risks and side effects, try to write them so subjects understand what side effects they are most likely to have, which they are less likely to have, and which ones they should report right away because they could be signs of rare but serious problems.
- Spell out acronyms and abbreviations the first time they are used.
- Try not to use graphs or tables. If you must use them, keep them simple.



- Use measurement terms that subjects will understand such as “teaspoon” or “Tablespoon” instead of “mL.”
- Use headings when you format the document so it is easy to see the basic parts of the form.
- Use bold font or underline any important information so that it stands out.
- Check the reading level of your consent document to be sure it reads at an 8th grade level or lower. This can be done in MS Word by doing the following:
  - ◇ On the **Tools** menu, click **Options**, and then click the **Spelling & Grammar** tab.
  - ◇ Select the **Check grammar with spelling** check box.
  - ◇ Select the **Show readability statistics** check box, and then click **OK**.
  - ◇ On the **Standard** toolbar click **Spelling and Grammar** .
  - ◇ When Microsoft Word is finished checking spelling and grammar, it shows information about the reading level of the document.

**NOTE:** Keep in mind that getting “Informed Consent” from a subject is a “Process.” It is not just about getting a signature on the consent document. The “Informed Consent Process” starts when the protocol is written to include procedures for initially informing the subject about the study and keeping the subject informed throughout the course of the study. In particular, the subject must be given any new information about the study that might change his/her mind about continuing to participate in the study. At any time during the study the subject should also be able to ask questions. This is also part of the informed consent process.

See the next page for a short “Lay-term” glossary.

Lay-term glossaries that contain more words and phrases can be found online. For example: The University of California at Davis offers one at:

<http://ovcr.ucdavis.edu/home.cfm?id=OVC,1,1063,1064>

## SOME DIFFICULT WORDS/PHRASES AND ALTERNATIVES

A Substantial portion of	Many	Involved in	Part of
Administered	Given	Is not associated with	Does not cause
Adverse	Bad	Likelihood	Chance of
Approximately	About	Minimize	Make less
Arise	Happen	Monetary	Money
Assess	Measure	Monitor	Measure
Benefit	Help	Observations	Watching
Calculated	Figured	Opportunity	Chance
Catheter	Thin tube	Participants will	You will
Characteristics	Problems	Participate	Be, take part
Characterize	Find out	Performed	Done
Compensation	Payment, income, benefits	Perceive	Think, feel
Completed	Finished	Preliminary	First
Concerning	About	Prior to	Before
Conducted	Done	Procedures	Tests
Confidential	Kept secret	Produced by	From
Designed	Planned	Provided	Given
Determine if you experience	Find out if you have	Receive	Get
Determine the effect of	Find out what happens	Recruited for	In
Develop	Learn, result	Regarding	About
Discontinue	Drop, stop	Required	Need made
Discuss	Talk about	Research procedure	Study
Escort	Take	Revealed	Told
Examine	Measure	Seeking	Trying, looking
Exhibit	Show	Sensation	Feeling
Experience	Feel, notice	Significant	Important
Five occasions	5 times	Strategies	Ways
Frequently encountered	Common, usual	Temporary	Short
Further	More	Terminated	Stopped
Immediately before	Just before	The information gained may help physicians better understand	We may learn
In the event that	If	Voluntary	Up to you
Indicated	Shown	Unacceptable	Too much
Informed	Told	Unusual situations	Problems
Initially	First	Waive rights	Give up rights
Inquiries	Questions	Who are the diagnosed as having	With
Instructed	Told	With regard to	About
Interfering	Changing	Withdraw	Drop out, quit
Interviewed	Talked to	Venipuncture	Blood drawn from a vein by needle stick
Involves	Uses		

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*Comments and suggestions for future “HRPP Topics” are welcome and should be submitted to:  
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