

## 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 a 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 – 11 pt          |
- Use simple words.
- Keep sentences short.
- As much as 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 myalgia,” say “you might have muscle aches”). 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 kinds of questions that will be asked, and how many hours the study will take than the real names of the tests or the names of the questionnaires they will fill out.
- 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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