

Writing Good at a Seventh-Grade Reading Level

By Norman M. Goldfarb and William H. DuBay

Dr. Smith wants to ensure that the informed consent form (ICF) for his study is as understandable as possible for the average U.S. adult to read. He hires the country's leading expert to write the document. He tests it on a 100 people with average reading skills. Based on the results, his expert refines the ICF. After five iterations, Dr. Smith is satisfied that he can improve it no further. He submits it to his IRB. The IRB runs the ICF through Microsoft Word's readability tool. MS Word gives it a score of grade 10. The ICF tells Dr. Smith to revise the ICF so it scores no higher than grade 8. Dr. Smith revises the ICF to achieve the grade 8 score. The document is harder to understand, but it meets the score. The IRB is satisfied.

U.S. regulations and ICH guidelines require that informed consent forms be understandable to potential subjects. Because the average American reads at the seventh- or eighth-grade level, an informed consent form written at that reading level, as measured by Microsoft Word's readability tool, is generally considered to be compliant with the regulations.¹

Software tools measure readability by counting things such as the average number of characters per word and the number of words per sentence. The readability experts who developed these tools recommend that they be used only for guidance. They strongly advise against slavishly "writing to the formula".

Leaving aside tricks you can play on the tools, good writers know that a mechanical rule such as breaking up long sentences into short ones does not necessarily make for more readable prose. Meaning can get lost betwixt short, choppy sentences. Similarly, the word "betwixt" scores better than "in between", but how many eighth graders know that word?

The following consent form example passages are from an ICF that, overall, scores at the seventh-grade reading level. The authors probably adapted it from the dense prose found in most informed consent forms. They deserve kudos for the effort, but "writing to the formula" has led them astray. Too many short sentences give paragraphs a "See Dick Run. See Jane Run. See Dick and Jane chase Spot." quality. A single longer sentence such as "See Dick and Jane try to catch Spot." can convey the meaning more clearly.

Each example below is followed by two revised versions. The first revision is more understandable, but uses longer sentences that do not score as well. The second revision demonstrates how good writing achieves the best of both worlds. (Note: With passages this short, minor changes in the text can cause major changes in the Flesch-Kincaid grade level scores.)

Example 1

Original (15 sentences, 146 words, 9.7 words/sentence, 6.8 Flesch-Kincaid grade level):

This consent form gives you information about the study. It tells you about the purposes, risks, and benefits of this research study. Regular care is based on the best-known treatment. The main goal of regular care is to help the individual patient. The main goal of research studies is to learn more so that we can help future patients. You might benefit from being in the study, but we cannot promise this. Your participation is voluntary. You don't have to be in this research study. You

can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change. Please read this consent form carefully. Ask any questions you have before you make a decision. The study doctor will answer your questions. You may consult with your family and friends.

Revision 1 (8 sentences, 123 words, 15.5 words/sentence, 8.7 Flesch-Kincaid grade level):

This consent form tells you about the purposes, risks and benefits of this research study. Regular care is the best treatment for each patient, while research studies develop treatments for future patients. You might or might not be helped by being in this study. Because your participation is voluntary, you don't have to be in this research study. You can decide to be in the study now, but change your mind later. Your decision to be in this study or not to be in this study will not affect your treatment or your doctor's attitudes about you. Read this consent form carefully and talk with your family or friends about it. Your study doctor will answer any questions before you make a decision.

Longer sentences can help economize on words. As consent forms become longer, their bulk can overwhelm the reader.

Revision 2 (11 sentences, 132 words, 12.0 words/sentence, 5.6 Flesch-Kincaid grade level)

If you sign this consent form, it means:

- You have reviewed the purposes, risks and benefits of joining this study.
- You can explain the difference between regular care – the best treatment for each patient – and research studies – to develop treatments for future patients.
- This study may or may not help you. You may be injured.
- You are joining the study freely, of your own free will.
- You are free to change your mind later and leave the study at any time.
- If you do not join the study, your treatment and your doctor's attitudes about you will not change.
- You are not signing away your rights to sue if you are injured.

Read this form carefully. Discuss it with your family or close friends. Your doctor can answer any questions you have.

Example 2

Original (2 sentences, 16 words, 8 words/sentence, 3.0 Flesch-Kincaid grade level):

If you are pregnant, you cannot be in this study. [Study drug] may cause birth defects.

Revision 1 (1 sentence, 17 words, 17 words/sentence, 7.0 Flesch-Kincaid grade level):

Because [study drug] may cause birth defects, you cannot be in this study if you are pregnant.

The point here is that pregnancy plus study drug might equal birth defect. This meaning is best conveyed by logically connecting the three concepts in a single sentence; poor readers have trouble making such connections across sentences.

Revision 2 (2 sentence, 19 words, 9.5 words/sentence, 4.2 Flesch-Kincaid grade level):

This drug may cause birth defects. Because of this, you cannot be in this study if you are pregnant.

Example 3

Original (7 sentences, 98 words, 14.0 words/sentence, 5.5 Flesch-Kincaid grade level):

After these tests, we will give you fluid through a blood vessel in your body. This process is called an IV infusion. An IV Infusion means sticking you with a needle to place a small tube into a blood vessel. We then run fluid through the tube into your blood. In this study, the fluid you get might contain [study drug] or it might not. You have an equal chance of getting [study drug] or getting fluid with no medication in it. Which one you get will be decided by chance (like by the flipping of a coin.)

Revision 1 (4 sentences, 56 words, 14.0 words/sentence, 5.6 Flesch-Kincaid grade level):

After these tests, we will give you an IV infusion. In this process, we will use a needle to put a small tube into a vein in your arm. We'll run fluid – either the study drug or salt water – through that tube into your blood stream. You have a 50-50 chance of getting the study drug.

The author achieves the software readability goal with lots of short sentences. The better solution is to remove the extra words that clutter the paragraph and hide the meaning.

Revision 2 (6 sentences, 62 words, 10.3 words/sentence, 4.4 Flesch-Kincaid Grade score)

After these tests, we will give you an IV infusion. That means we will inject some liquid into your vein with a needle and a small tube. Some people will get the drug we are studying. Others will get salt water. In this way, we can tell if the drug works or not. You have a 50-50 chance of getting the drug.

Example 4

Original (5 sentences, 75 words, 15 words/sentence, 7.8 Flesch-Kincaid grade level):

You might be injured by being in this study. If you are, we will bill your medical insurance for the cost of treating your injury. Some insurance does not pay for injuries caused by research. Whatever your insurance does not pay, [Sponsor] will pay only if you followed the doctor's instructions. [Site] does not have a policy to pay you if you have an injury or other bad effects because of being in the study.

Revision 1 (5 sentences, 78 words, 15.6 words/sentence, 8.4 Flesch-Kincaid grade level):

Being in this study may injure you. If you are injured and you have medical insurance, we will bill your insurance company for the cost of treating your injury. If your insurance company does not pay, [Sponsor] will pay, but only if you followed the doctor's instructions. [Site] does not have a policy to pay for treating injuries caused by the study. However, by signing this consent form, you do not give up any of your legal rights.

It's not just the number of words in the sentence, but the choice and order of the words. The revised version consolidates the five sentences in the original text into four sentences. It adds a common and important non-exculpatory sentence that the original left out.

Revision 2 (5 sentences, 43 words, 8.6 words/sentence, 3.9 Flesch-Kincaid grade level):

If you are injured by this study:

- If you have insurance, it will probably pay.
- If insurance doesn't pay, [Sponsor] will pay if you followed the doctor's instructions.
- [Site] does not plan to pay.

- You still have the right to sue for injuries.

Conclusion

The English language – or any language – is too complex to be reduced to a simple understandability formula. The formulae have their uses; they make us aware of what we write at the level of words and sentences. Understandable writing also depends on factors such as organization, style, word-choice, and page design. Documents must be written for a specific audience. The formulae can help, but only if applied intelligently. Unintelligent uses include:

- Destroying meaning by mechanically chopping long sentences into small pieces
- Omitting important information
- Adding extra words to bridge the gap between sentences that belong together
- Substituting mechanical editing for the hard work of drafting clear and meaningful prose

Much of the material in consent forms is standard and can be reused. At minimum, the standard text should be written for maximum understandability. Unfortunately, good writing takes effort, and is best performed by good writers. Fortunately, numerous good writers are available through the American Medical Writers Association and the European Medical Writers Association.

Please send examples of well-written consent forms – or pieces thereof – to ngoldfarb@firstclinical.com. Just make sure they don't look like this:

Consent forms can be written. They can be written for a grade seven reading level. They can be written for a grade eight reading level. These are low levels. They are average U.S. levels. "Writing to the formula" can reduce understanding. That defeats informed consent. That is bad. Don't do it. (Flesch-Kincaid grade level 5.3)

Acknowledgement

We gratefully acknowledge Mark Hochhauser, readability consultant, for his contributions to this article.

Reference

1. "How Well Does the Average U.S. Adult Read?", Norman M. Goldfarb, The Journal of Clinical Research Best Practices , September 2005

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting, training, implementation and research services. Contact him at (650) 465-0119 or ngoldfarb@firstclinical.com. William H. DuBay is a readability consultant. Contact him at (949) 631-3309 or bdubay_92627@yahoo.com.