Making Research Consent Forms More Readable

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Research consent forms are becoming increasingly long, complex, and difficult to understand. Many are written at a high reading level and use technical language. Factors associated with decreased comprehension of consent forms include limited education, increasing age of the patient, and the readability of the consent form **(1)**. This paper focuses on simple but effective ways to make research consent forms more readable. The readability of a consent form is only one of several parts of the informed consent process. Explaining the research verbally and face to face to the subject and assessing the subject's understanding and competency are essential to confirm that the subject understands and voluntarily agrees to the potential risks of participating in the research and appreciates that the research may not directly benefit the subject. For some subjects, use of creative audiovisual aids may be necessary to enhance comprehension when a procedure is complex.

Background

Informed consent, the foundation of ethical research, includes four major elements: disclosure of essential information to the subject, comprehension, competency, and voluntarism. According to the Nuremberg Code, the subject should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision **(2)**. Informed consent implies not only the imparting of information by the researcher but also assessing the subject's comprehension of the benefits and risks of and alternatives to participating in the research. The U.S. Department of Health and Human Services regulations relating to research of human subjects (21 C.F.R. Section 50.20) state that the information that is given to the subject or the representative shall be in language understandable to the subject or representative. The information presented to the subject should be written at a reading level understandable to the subject, use lay terminology, not professional jargon, and be worded without loaded terms that might coerce a subject into participating in the study without understanding its terms.

The average reading level among U.S. adults is no higher than the eighth grade. Among Medicaid enrollees, the average reading level is even lower, about the fifth grade **(3)**. Many subjects do not understand research consent forms because these forms are typically written at the college or graduate school level **(3-7)**. It is the principal investigator's responsibility to see that subjects have an adequate understanding of the procedures, risks, and benefits before they participate in the study. Researchers should strive to write consent forms at a sixth to eighth grade level unless their potential subjects

are known to read at a much higher or lower reading level. Studies show that even highly literate subjects are not usually offended by simple material **(1, 8).**

Writing research consent forms with a low level of reading difficulty is a skill that can be learned. The information below includes simple but powerful strategies to reduce reading levels for consent forms. Poor and improved examples of paragraphs from a research consent form are also included.

Assessing Reading Level

Computer programs can be used to quickly assess the reading level of a consent form. However, one of the best ways to understand how to lower reading level is to calculate the reading level of several documents by hand. The factors that contribute to high and low reading levels then become apparent. Numerous readability formulas such as the SMOG, the Fog, the Fry, and the Flesch-Kincaid are available, and the reliability among these formulas is high **(9).** These formulas calculate reading grade level primarily based on the number of words with more than two syllables and by sentence length. To reduce reading level, it is important to substitute short words for long words and short sentences for long sentences. In research consent forms, it is difficult, if not impossible, to avoid some long words such as chemotherapy, angioplasty, and infarction. When long words are used, they should be defined using simple terms. Shorter but unfamiliar words, such as the term "random," also should be clearly defined.

Calculating Readability Using a Computer Program

If you are using Word Perfect, highlight, in order: Tools, Grammatik, View, Statistics, and Readability.

If you are using Microsoft Word, highlight, in order: Tools, Options, Spelling and Grammar, Grammar with Spelling, Show Readability, OK, Spelling ABC.

Calculating Readability Level Using the SMOG Formula

To use the SMOG formula to manually assess reading level, follow these 4 steps:

1. Count 10 consecutive sentences near the beginning, middle, and end of the consent form (total=30 sentences).
2. Count every word of three or more syllables in the 30 sentences. If a word is repeated, count the repetition also. Proper nouns, if polysyllabic, should be counted. Hyphenated words are considered as one word.
3. Obtain the square root of the number of words with 3 or more syllables.
4. Add "3" to the Square root. This gives you the SMOG readability level.

Example

You count 72 words with 3 or more syllables from 30 sentences.
The square root of 72 = 8.5.
The reading grade level is 11.5 (8.5 + 3 = 11.5).

Samples of Different Reading Levels (10)

College: With the onset of nausea, diarrhea, or other gastrointestinal disturbances, consult your physician immediately.

8th Grade: If you start having nausea, loose bowel movements, or other stomach or bowel problems, call you doctor immediately.

4th Grade: If you start having an upset stomach, loose bowel movements, or other problems, call your doctor right away.

Strategies to Reduce Reading Difficulty (4-5, 8-10)
The following approaches are suggested to lower reading level:

1. **Calculate reading level**
   *Calculate the reading level of the consent form using a manual approach or one of the computer readability tools. Identify and fix problem areas. (Indicate the reading grade level when you submit your consent form to the IRB). (Note: The Flesch-Kincaid Reading Level of this paper is 9.9).

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2. **Format**
   *Use adequate spacing and white space to make content inviting to read. Avoid crowding of words and letters.
   *Use headings/subtitles. These reduce content density and serve as "road signs."
   *Use lists rather than paragraphs when possible.

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3. **Sentences/Paragraphs/Print Size & Type**
   *Use short sentences (no more than 20 words/sentence).
   *Use short paragraphs (no more than 10 lines/paragraph).
   *Use large print size (12 point or larger) (this paper is written in 12 point).
   *Use clean, easy to read print type, preferably a serif font (serifs are the little bars on the tops and bottoms of letters). Examples include Times New Roman (the font used for this paper) and Bookman Old Style.
   *AVOID USING ALL CAPITALS (HARD TO READ). Only use capitals when grammatically indicated.
   *Avoid use of **bold type** which can lead to subjects overlooking information not in bold type.

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4. **Person/Voice**
   *Use second person (you) rather than first person (I) or third person (the patient, the subject).
   *Use active voice rather than passive. Write the way you would talk.

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5. **Abbreviations**
   *Spell out abbreviated terms the first time you use them with the abbreviation in parentheses after the word(s), e.g., Food and Drug Administration (FDA) or continuous positive airway pressure (CPAP).

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6. **Type of Information**

*Focus on priority, "need to know" information. Omit nonessential information such as complex theoretical background.

7. **Research Lingo**

*Avoid research lingo such as "arms of a trial." For research lingo that must be used, define each term. For example, randomize (as if by tossing a coin, or as if in a lottery); placebo (an inactive substance such as a sugar pill). If a placebo is used, note the chance of receiving the placebo, e.g., you will have a 1 in 4 chance of receiving the placebo.

8. **Prefer Short Words**

*Use words with 1-2 syllables rather than longer words. Prefer common, familiar words to less common, less familiar words (a Thesaurus is helpful). For example:

Avoid	**Prefer**
administer	give
anticipate	expect
ascertain	find out
commence	begin, start
determine	find out, see if
difficulties	problems
discontinue	stop
endeavor	try
evaluate	assess
experience	have
indicate	show
induce	cause
investigation	study
in conjunction with	at the same time
is experienced	occurs
manifest	appear
minimize	lower, reduce
participate	be in, take part
physician	doctor
require	need
terminate	stop
utilize	use

9. **Avoid Complex Medical Terminology**

*Avoid medical terminology whenever possible. If a medical term must be used, for example, angioplasty, antibodies, sentinel lymph node, etc., define/explain it.

Avoid	Prefer
anorexia	lack of appetite
chemotherapeutic agent	anticancer drug
edema	swelling
insomnia	trouble sleeping
intradermal	under the skin
malignancy	cancer
postoperative	after surgery
subcutaneous	under the skin
venipuncture	draw blood

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10. Avoid Empty Phrases:

Avoid	Prefer
despite the fact that	although
for the purpose of	for
on account of the fact that	because
was of the opinion that	believed
with the exception of	except

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11. Pictures

*Consider including simple illustrations and/or diagrams.

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12. Numbers

*Use numerals rather than words for numbers, e.g. "10" instead of "ten" and "1 out of 4" instead of "one out of four." (However, if the first word of a sentence is a numeral, the word form of the numeral is preferred.)

Hard to Read and Improved Examples of Research Consent Form Paragraphs

Examples of hard to read and improved research consent form information are shown below to further assist researchers:

Hard to Read:
Purpose:
The purpose of this study is to 1) evaluate the effectiveness of 12.5 and 25 mg daily of AB-000 for treatment of rheumatoid arthritis; 2) to evaluate the safety of AB-0000 at daily doses of 12.5 to 50 mg over a full year in the rheumatoid arthritis patient; 3) to evaluate the effectiveness of increasing daily doses of MK-0000 from 12.5 mg to 25 mg and from AB-0000 25 mg to 50 mg for treatment of rheumatoid arthritis; and 4) to evaluate the maintenance of therapeutic effects of AB-0000 25 and 50 mg daily, and Naproxen 500 mg twice daily, over a treatment period of one (1) year.

Improved:
Purpose:
The purpose of this research is to study the effectiveness of different doses of a study drug called AB-0000 compared with a drug called Naproxen and compared with a placebo. The study drug has been approved by the U.S. Food & Drug Administration (FDA) only for research with a limited number of patients. Naproxen is a drug that is approved by the FDA for treatment of rheumatoid arthritis. A placebo is an inactive substance (similar to a sugar pill) that is made to look like the study drug.

Hard to Read:
What you will be asked to do if you are in this study:
Your participation in this study will last approximately one year (52 weeks of study therapy). During the first twelve weeks of the study, you will receive either AB-0000 12.5 mg daily, AB-0000 25 mg daily, Naproxen 500 mg twice daily or placebo (a Afake≅ medicine and the same as receiving sugar pills). Your chances of receiving the placebo are one in three. Your chances of receiving 25 mg AB-0000 daily are also one in three. Your chances of receiving 12.5 mg AB-0000 daily are one in six and for receiving Naproxen 500 mg twice daily are one in six. The study medication will be taken twice daily (three tablets in the morning and one tablet in the evening). Neither you nor your doctor will know if you are taking AB-0000, Naproxen, or placebo. However, in an emergency, your physician can ascertain what you are taking by contacting the pharmacist at Presbyterian Hospital of Dallas.

Improved:

What you will be asked to do if you are in this study:

This study will last 1 year. During the first 12 weeks of the study you will take 4 tablets per day in 1 of the following combinations :

1. One tablet of AB-0000 12.5 mg once per day and 3 tablets of a placebo. (Your chance of receiving this is 1 is 6.)
2. One tablet of AB-0000 25 mg once per day and 3 tablets of a placebo. (Your chance of receiving this is 1 in 3.)
3. One tablet of Naproxen twice per day and 2 tablets of a placebo. (Your chance of receiving this is 1 in 6.)
4. Four tablets of a placebo. A placebo is an inactive substances that looks like the other drugs. (You chance of receiving this is 1 in 3.)

Neither you nor your doctor will know if you are taking AB-0000, Naproxen, or the placebo. However, in an emergency, your doctor can find out what you are taking from the pharmacist at Presbyterian Hospital of Dallas.

Conclusion

Striving to see that subjects are fully informed before they participate in research has been, and will continue to be, a challenge for investigators involved in medical research. We hope the information in this paper will help researchers prepare research consent forms that are written at an appropriate reading level for subjects. A simple, clear, comprehensive consent form, written at a low level of reading difficulty, should help speed the IRB approval process.

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July 1999; revised May 2003 EHW