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Too Many Unnecessary Words = Confusing Consent Forms

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Regulators and IRBs recommend readability formulas to ensure that consent forms are written at comprehensible reading levels. But these formulas count only syllables per word, words per sentence, or the percentage of polysyllable words. They weren't designed to address sentence construction or unnecessary words. Yet after being on an IRB for over 13 years, I'm still troubled by the terrible writing I find in most consent forms.

Typical consent forms include language such as "This consent form may contain words that you do not understand. Please ask [study doctor] or his staff involved with the clinical research trial to explain any words that you do not understand before signing this form." But hard-to-understand individual words are not as big a comprehension problem as the convoluted and redundant language used to create badly written sentences.

I've included examples of bad writing from seven consent forms along with rewritten versions that I hope make more sense. Of course my revisions aren't the best or only way to rewrite the examples; write your own improved versions—including better grammar and punctuation. Try using as few words as needed instead of as many words as possible.

Read and re-read the examples I've included. Since you're familiar with consent forms you already know what's covered in the consent form, and you can probably understand what the consent writers tried to say even if they couldn't say it. But after carefully reading these examples you may discover that they don't actually mean what you thought they meant.

Example #1
How many people will take part in the study?
"This study will have two parts. The first part, called Phase I is now concluded. The second part, called phase II, of the study will include two groups of patients; the first group of patients, Cohort A, will include approximately 37 subjects who have not received prior treatment with chemotherapy, and the second group of patients, Cohort B, will include approximately 28 subjects who have received and progressed during treatment with [study drug]." (73 words).

Or "This study has two parts; Part I is done but Part II has two groups of patients. Group A includes about 37 subjects who didn't get chemotherapy. Group B includes about 28 subjects who were treated and progressed with the [study drug]." (42 words)

Example #2
Study procedures
"If you are a woman of childbearing potential, a blood sample will be taken to determine whether you are pregnant. If the pregnancy test is positive, you will not be able to be in the study. Also, women who are breastfeeding will not be able to be in the study." (50 words).

Or "We'll take blood to see if you're pregnant because you can't be in the study if you're pregnant or breastfeeding." (20 words)

Example #3
Risks Associated with the Study:
"If you have a complicated infection in your abdomen caused by an intestinal perforation; or hole in your intestine, your doctor will treat you with caution. In past studies involving 1700 patients with [infection], 6 patients treated with [antibiotic] and 2 patients treated with the other study drugs presented with intestinal perforations and developed a serious infection in the blood that may be life-threatening. However, because of patient differences before treatment was started, the relationship of these events to study drug is not known." (84 words).

Or "Your doctor will treat you if you are infected from a hole in your intestine. Research on 1,700 patents found intestinal holes and serious infections in 6 subjects treated with [antibiotic] and 2 treated with the other study drugs. We don't know if the study drug caused the infections." (49 words)

Example #4

What happens if I am injured as a result of taking part in this research study?

"In the event you are injured as a direct result of the study drug or any clinical procedure properly performed according to the study plan, the study sponsor will pay reasonable medical costs such as doctor's fees and medical expenses needed to treat the injury. The treatment must be authorized by the study doctor except in the event of an emergency in which case the study doctor should be notified as soon as possible." (74 words)

Or "Call your study doctor immediately if you're injured by the study drug or procedure. Unless it's an emergency, the sponsor will pay reasonable medical costs (doctor's fees and medical treatment) but only if your study doctor authorizes that treatment." (39 words)

Example #5

Biomarker development.

"In order to develop new biomarker blood tests, about 4 teaspoonfuls of blood will be obtained at screening, week 2, week 9, and every 8 weeks thereafter, at discontinuation of the [study drug] or placebo or any reason and at the safety follow up visit. In addition, when available, a portion of your previously removed tumor and a portion of your tumor, if you consent to undergo a biopsy and the corresponding pathology report will be collected and analyzed." (79 words)

Or "To develop new blood tests, we'll draw 4 teaspoons of blood during screening, every 2 to 8 weeks after that, when [study drug] or placebo treatment ends, at your follow up visit, or for any other reason. If you agree to biopsies, we'll analyze samples from your removed and current tumors." (51 words).

Example #6

Are There Benefits To Taking Part in the Study?

"Participation in this study may allow your cancer to improve. This however may not occur, and it may not be permanent if it does. It is hoped that this study will produce information that may lead to a more effective treatment of your disease. You may receive no direct benefits from participating in this study. However, it (sic) this study may produce information that could lead to more effective treatment for other cancer patients in the future." (77 words)

Or "You may not benefit from being in this study, although your cancer might temporarily improve. We hope this study will produce more effective cancer treatments." (25 words)

Example #7

Voluntary Participation and Early Withdrawal

"Taking part in this research study is voluntary and you may refuse to take part in this study without any effect on your current or future medical care. If you agree to take part in the study, you may discontinue taking your study medication or you may withdraw your consent to participate in the study at any time and for any reason. You may take either of these actions without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care." (90 words)

Or, "Being in this study is voluntary. You will not lose any medical benefits or affect your medical care if you refuse to be in the study, if you stop taking the study drug, or if you withdraw your consent during the study." (42 words)

Do consent forms match the consent process?

Badly written consent forms aren't just about pieces of paper; they're about how the written informed consent form matches (or doesn't match) consent information discussed during the consent process. Ambiguous written consent information means that if prospective subjects don't understand what was discussed during the consent process, relying on their consent form for explanations may not help much.

Communicating clearly with prospective subjects requires researchers to translate consent form language into language that's more understandable and meaningful. But if you're confused by some of the above examples, prospective subjects will have even a harder time trying to understand that confusing language. If researchers can't understand the language how can they accurately explain the research during the consent process?