U-MIC TRANSCRIPT
Writing Informed Consent Documents
Part Two: Exhibit

The previous presentation outlined some basic ideas that it's helpful to keep in mind when writing and revising informed consent documents. It distinguished between reading a text and comprehending its message, and identified four characteristics of readable and comprehensible consent language: accessibility, brevity, clarity, and directness.

This presentation will demonstrate how these basic ideas might come into play in writing and revising a consent document. Over the next ten minutes or so, we will

- read through an example of problematic consent language
- identify some of the barriers to readability and comprehensibility
- and, finally, address these problems in revision

We begin with the following passage from a fictional informed consent document:

> **Study purpose**
>
> This study is aimed at assessing the effectiveness of an oral pharmacological agent for the treatment of xerostomia. To this end, subjects will be asked to self-administer 25 mg nozerost or placebo twice daily (a.m. and p.m.) over a six-week period, and will record dry mouth symptoms—indicating their severity on a five-point scale—in a daily journal. Xerostomia has in past research been found to be prevalent among approximately 24% of U.S. adult females and approximately 18% of U.S. adult males up to 88 years of age. Available data suggest a link between low salivary flow and xerostomia in adults toward the lower end of the age spectrum studied, whereas a more complex constellation of factors (including but not limited to low salivary flow) in older and elderly adults may contribute to xerostomic symptoms. Xerostomia is a known side effect of a range of prescription and over-the-counter medications, and is also associated with various medical conditions, such as diabetes and Parkinson's disease. Development of a topical anti-xerostomic formula comparable in its effects with the oral agent under examination in this study is not currently foreseen by the researchers.

Whereas effective informed consent language tends to be accessible, brief, clear, and direct, this passage is technical, wordy, disorganized, and a little vague. Improving it will call for

- replacing technical and academic terminology with familiar, everyday language—or, where some technical terms are unavoidable, providing clear definitions
- trimming inessential detail
- rewriting complex sentences as shorter, simpler sentences
- presenting information in a logical structure, taking care to stay on topic
- and making simple, affirmative statements, delivered directly from author to reader, and favoring the active voice

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Before we begin rewriting, we'll want to reduce the passage to content that is essential to the informed consent process. In the middle of the passage, we encounter some statistical and demographic information. In some cases, details like these may factor significantly in an individual's decision whether to become a subject; however, since this study is designed to evaluate the effectiveness of a drug, it's probably safe to remove these details from the consent document.

The final sentence is not only complicated but, because it relates to something that will *not* be part of this study—the researchers *do not* plan to produce the drug in topical form—probably isn't essential for informed consent purposes. We may therefore decide to remove it.

Sentence two conveys important information that potential subjects will certainly need to consider; but it relates more to procedures than to the purpose of the study. Although we won't discard this sentence completely, we should move it out of this part of the document and into a separate description of study procedures.

Having now reduced the passage to essential content, it's a good idea to look for terms or phrases that are either technical or uncommon in everyday speech. As we rewrite, we'll try to find more familiar substitutes, and, where some technical terminology is unavoidable, we'll need to supply simple definitions.

Our revised draft might begin with some background on the condition.

> Dry mouth (xerostomia) affects many adults in the United States.

Here, we do more than just define the technical term *xerostomia*: because early in the document we present the condition in plain language, enclosing the technical term in parentheses, we can plan to use the more familiar phrase—"dry mouth"—for the remainder of the document. Notice that the original passage referred to the condition mostly by its technical name, but in one instance—"and will record dry mouth symptoms"—switched to the familiar phrase. Choosing a single term to use consistently throughout the document will help readers keep track of the concept as they read.

To further explain the condition, we might reposition the information about causes of dry mouth from its original place near the end of the passage to our revised introductory paragraph.

> It often occurs as a side effect of medicine. Certain health conditions, such as diabetes and Parkinson's disease, can also cause dry mouth.

Now that we've given the reader a basic understanding of the condition, we're ready to explain the purpose of this particular study in a new paragraph.

> In this study, we want to find out how helpful a drug called nozerost might be in treating dry mouth.

In many cases, this short summary is about as detailed as the study purpose portion of a consent document needs to be, although some more complex studies may call for further explanation.

At this point, we shift to the procedures portion of the document and revise the original sentence two. Generally, readers will more easily read and understand a sentence that conveys a single idea than a complex sentence that combines numerous ideas. Sentence two is densely packed and presents the reader with several ideas that we'll want to address separately in our revision.

> If you decide to take part in this study, we'll give you a six-week supply of pills to take at home. The pills will be either nozerost (25 milligrams each) or a placebo.

At this point, we've come to a term—*placebo*—that we need to define.

> A placebo is a fake drug. It looks exactly like the real drug but contains no medicine. We'll use a random method (like a flipping a coin) to decide whether to give you the real nozerost or the placebo. You'll have no way of knowing which one you receive.

Notice that the original sentence neither defined *placebo* nor explained how researchers will determine whether a subject receives nozerost or the placebo.

We now start a new paragraph, which will address when subjects should plan to take the study drug.

> You'll take two pills every day for the next six weeks. You should take one pill when you get up in the morning and the other pill around dinnertime.

The original passage conveyed this information using a few words within a very complicated sentence; the revision isolates these important details to make them more conspicuous to the reader.

In the final revised paragraph, we can address the remainder of the procedures information:

> We'll also ask you to write down your dry mouth symptoms every day in a journal. Next to each symptom, you'll say how bad it is on a scale of 1 to 5.

Keep in mind that there are likely to be additional procedures—and other required elements—to address in the consent document; this revision includes only the information that we've taken from the original study purpose passage.

Microsoft Word's readability statistics provide some basic information about the anatomy of a text, which can serve as a very general guide for achieving an appropriate reading level.

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The first thing we notice in comparing the original and revised drafts is that their word counts have turned out to be similar. Even though we cut some fairly large portions of the original passage, our revision makes a point to define *placebo* and briefly to explain randomization, which the original passage neglected to do.

Overall, the Flesch-Kincaid system finds the original draft to read at about a graduate school level and the revised draft to be readable by most sixth-graders. We can account for this difference by reviewing the averages in the middle segment of the statistics box: the revised draft consists of shorter words and considerably shorter sentences and paragraphs.

Always keep in mind that readability formulas like Flesch-Kincaid cannot provide a complete or wholly accurate sense of a text's readability, and they can tell you nothing about whether readers will comprehend your subject matter and message.

Contact the IRB for more information about writing informed consent documents.

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