U-MIC TRANSCRIPT
Writing Informed Consent Documents
Part One: Fundamentals

Federal regulations require researchers to obtain the informed consent of adult research subjects, unless the IRB has granted a waiver (45 CFR 46.116). In most cases, the consent process consists of two components: an ongoing series of discussions, usually in person, between study personnel and a subject or potential subject, as well as a written, IRB-approved informed consent document. Both FDA and OHRP regulations pertaining to consent expressly require that "the information that is given to the subject or the representative shall be in language understandable to the subject or the representative."

Since subjects' literacy skill levels can be varied and unpredictable, it's important to compose consent documents using simple and common language, in order to avoid confusing or overwhelming those subjects with more limited reading skills. This can be a challenge with studies that involve complex scientific concepts and uncommon anatomical or medical terms. If some unfamiliar language is unavoidable, consent document authors should be sure to define terms and concepts that non-specialists are unlikely to know, and informed consent discussions are a critical opportunity for researchers to gauge a subject's understanding and to clarify any points in the document that the subject hasn't fully understood.

It's generally accepted that most adults will have little difficulty reading language written at a junior high school reading level—somewhere between sixth and eighth grade. The readability statistics that Microsoft Word generates automatically, based largely on a readability formula developed in the 1950s by Rudolf Flesch, may serve as a general guide for tailoring written language to the junior high level. Keep in mind, however, that formulas like the Flesch-Kincaid calculator are designed only to estimate the ease or difficulty with which most readers will navigate the text itself; no formula can reliably predict whether readers will grasp—and remember—the ideas and details that make up a document's content. Even a very readable document may not be comprehensible to all readers.

IRBMED's educational sessions on writing informed consent documents outline four characteristics of readable and comprehensible consent language:

- accessibility
- brevity
- clarity
- and directness

On the level of readability, accessible language favors vocabulary that fluent language speakers hear and use frequently. This means avoiding specialized terms, associated with a particular profession or expertise, as well as less common academic words familiar mainly to those with a high level of formal education. In terms of comprehensibility, creating accessible consent documents involves addressing only those details that are essential to equipping potential subjects to make informed decisions about whether to take part in a study. As with many aspects of consent writing, differentiating between those

study details that are essential for consent purposes and those that are not is a matter of judgment and calls for careful thought.

Like accessibility, brevity has a role in making a document both to easier read and easier to understand. The Flesch-Kincaid formula in Microsoft Word calculates readability by counting—counting letters per word, words per sentence, and sentences per paragraph—and associating smaller quantities with ease of reading. Likewise, subjects may find a short overall consent document easier to understand, since it's less likely to overburden their attention span and working memory.

Clarity in consent writing relates to organization. Simple and common sentence structure may make more immediate sense to readers than complex, rarer structures. Organizing content clearly—for example, describing study visits chronologically, or making a point early in the document to define terms or concepts likely to be unfamiliar—may help subjects conceptualize and remember the information.

Direct grammar and style tends to mean preferring the active voice over the passive—"we will take a blood sample," instead of "a blood sample will be taken"—and affirmative, rather than negative, statements, focusing on what is the case, instead of what is not. And a direct delivery of the message from author to reader—"*we* would like *you* to take part in a study," instead of "the researchers are looking for subjects"—can make the information in the document seem less remote and more clearly part of a real interaction between researchers and subjects.

Writing effective informed consent documents involves knowledge of one's subject population and careful judgments about language and concepts that subjects are likely to recognize. Keeping certain basic ideas in mind—such as the distinction between reading text and fully comprehending subject matter, or the benefits of written language that is accessible, brief, clear, and direct—may help consent document authors make better wording and document design choices for their subjects and potential subjects. Prescriptive style manuals, such as William Strunk's famous *Elements of Style* or Blake and Bly's *Elements of Technical Writing,* can also be useful. University of Michigan researchers whose studies are under IRBMED oversight may contact IRBMED's technical writer directly for suggestions for fine-tuning their informed consent documents in progress.

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