

SIMPLIFYING INFORMED CONSENT....IT'S NOT SO SIMPLE!

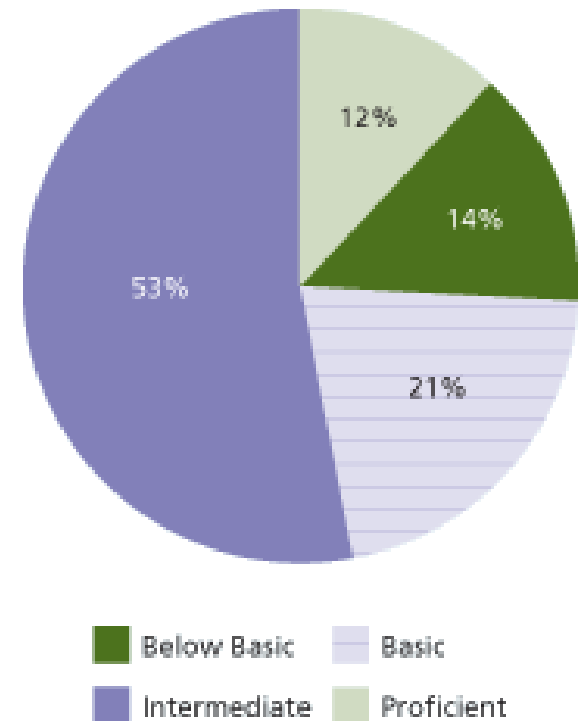


Here are the facts...

- ❑ Informed consents are complex, highly technical and often bogged down with legal and regulatory jargon
- ❑ Regulatory and legal requirements make ICF's longer, and harder to understand
- ❑ Although recommended to have ICF's at 8th grade level, most are not.**
- ❑ When looking to “simplify”- grade level is just the tip of the iceberg.

National Assessment of Adult Literacy (NAAL)- 2003- Health Literacy Results

- Intermediate- Read instructions on a prescription label, and determine what time a person can take the medication.53%
 - Basic-Read a pamphlet, and give two reasons a person with no symptoms should be tested for a disease.21%
 - Below Basic- Read a set of short instructions, and identify what is permissible to drink before a medical test.14%
 - Proficient- Using a table, calculate an employee's share of health insurance costs for a year.12%
-
- Limited health literacy affects adults in all racial and ethnic groups.
 - Compared to privately insured adults, both publicly insured and uninsured adults had lower health literacy skills.



But wait, there's more!

- Literacy statistics don't even take into account non-English speakers
- Diverse cultural differences of patient population
- Add in sponsor and institutional requirements for consent documents
- Therapeutic misconception
- Studies have found that just “simplifying” consent forms doesn't improve comprehension

So What Do We Do?

Subjects need to
UNDERSTAND the
information/ Need to
Simplify

Subjects have a RIGHT TO
KNOW and be given ALL
the information to give an
INFORMED consent

RESPECT FOR PERSONS

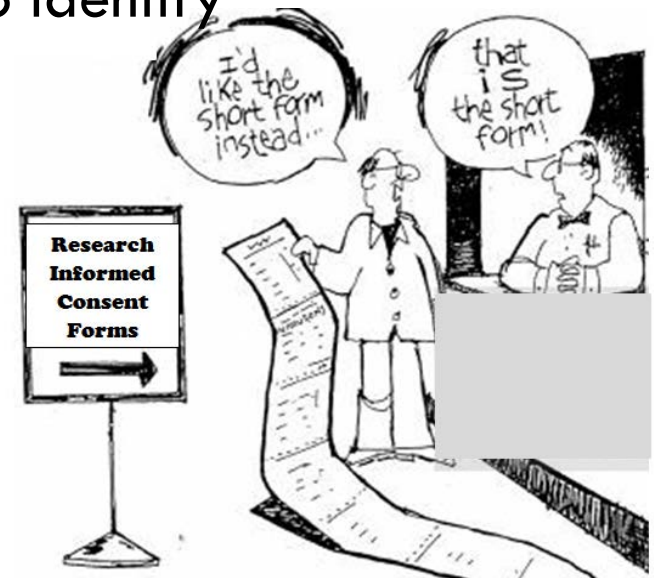


Caveats in using Readability Statistics

- ❑ Formulas do not take overall organization, formatting, or page density into account, all of which significantly impact readability.
- ❑ Sometimes we cannot avoid using multi-syllable words like “mammography” or “immunization.”
- ❑ The number of syllables does not always correspond to how easy a word is to read and understand. For instance, “comprise” is a two-syllable word that is often misunderstood.
- ❑ Similarly, the number of words does not always correspond to how easy a sentence is to read.

Caveats in using Readability Statistics

- The Flesch-Kincaid formula looks for periods to identify the end of a sentence. If your text includes a bulleted or numbered list, adding periods at the end of each item will yield a better score.
- If having difficulty identifying what “reads too high”- try checking each paragraph individually to identify problematic text.

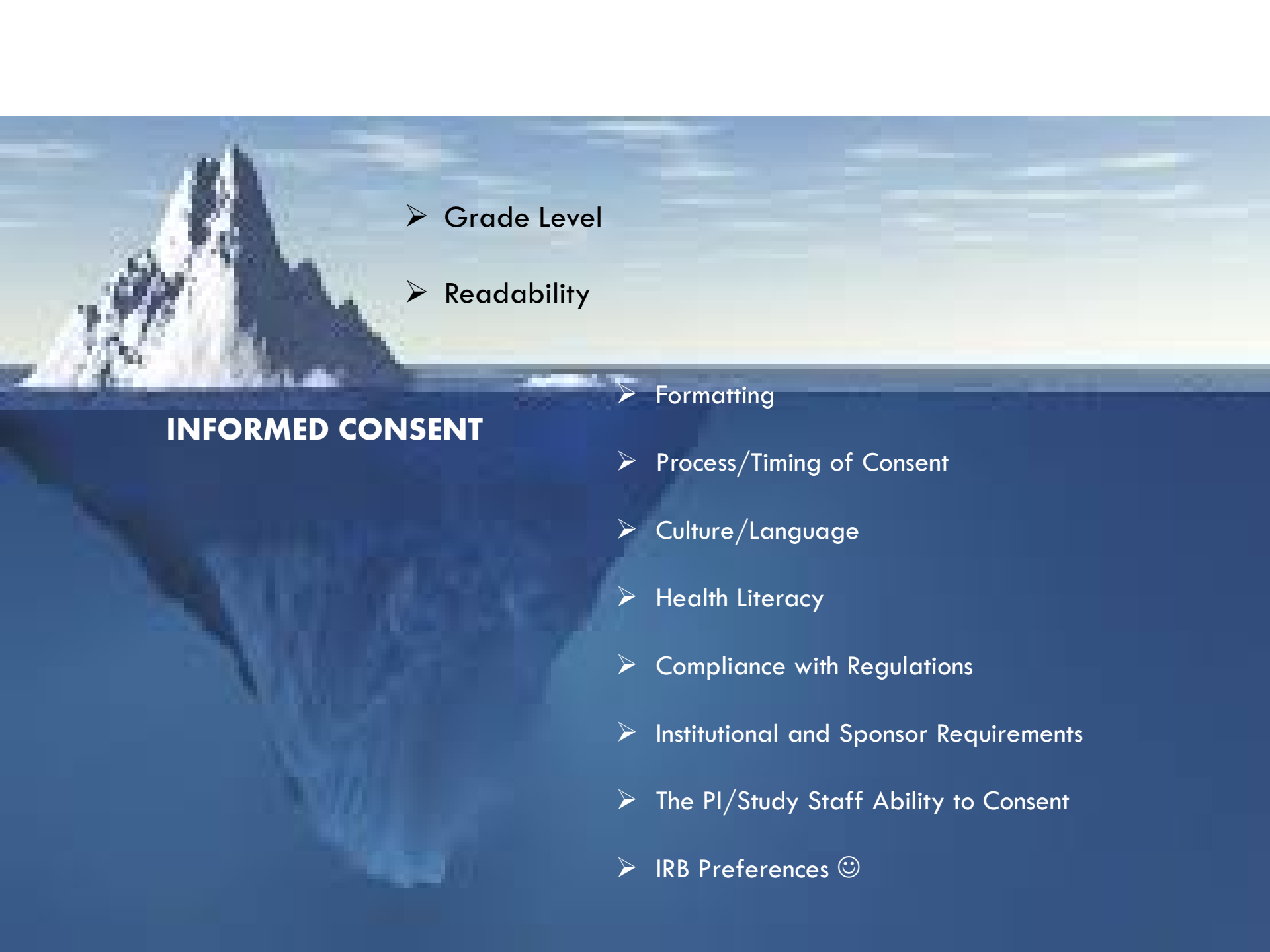


Beyond the Grade Level

- Replace jargon and other complex terms with familiar vocabulary (see links)
 - ▣ Plain language is written in a conversational style
 - ▣ Use an “active” voice (We will ask you about vs. You will be asked questions about...)
 - ▣ Organize the content in a way that will make sense to the reader
- Create single-topic paragraphs and concise sentences
 - ▣ Use short sentences
 - ▣ Limit paragraphs to one main idea.
- Use reader-friendly formatting-
 - ▣ Adequate white space and margins
 - ▣ Break up chunks of dense copy
 - ▣ Give your readers “road signs”
 - ▣ Emphasize important information

Others methods to help simplify the consent process...it's more than a form

- ❑ Encourage PI's to allow others to read consents
- ❑ Read them out loud
- ❑ IRB can request a consent training (for practice) prior to enrollment on a complex study
- ❑ Emphasize the process and educate PI's/study staff
- ❑ Be open to adding visuals, consent aids (videos, brochures, information sheets)
- ❑ Consider adding extended consent discussion times for complex studies (written into protocol)

An iceberg floating in the ocean. The tip of the iceberg, which is above the water line, is labeled with 'Grade Level' and 'Readability'. The much larger part of the iceberg, which is submerged below the water line, is labeled with 'INFORMED CONSENT' and a list of other factors: 'Formatting', 'Process/Timing of Consent', 'Culture/Language', 'Health Literacy', 'Compliance with Regulations', 'Institutional and Sponsor Requirements', 'The PI/Study Staff Ability to Consent', and 'IRB Preferences' with a smiley face emoji. This visual metaphor suggests that the visible aspects of informed consent are only a small part of the overall process.

➤ Grade Level

➤ Readability

INFORMED CONSENT

➤ Formatting

➤ Process/Timing of Consent

➤ Culture/Language

➤ Health Literacy

➤ Compliance with Regulations

➤ Institutional and Sponsor Requirements

➤ The PI/Study Staff Ability to Consent

➤ IRB Preferences 😊

Helpful Links!

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_ii.html

file:///C:/Users/103381/Documents/Education%20and%20Outreach%20Presentations/prism_readability_toolkit.pdf