



Informed Consent: Nuts and Bolts

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The views expressed in this talk are my own.
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Summary

- Consent is a process not a form
- The informed consent process is only one opportunity among many to convey respect to potential research subjects.

Best Practices

- Consent Form
 - Style
 - Format
- Promoting Understanding

Style

- Short sentences
- Short words
- Simplify text
- State main ideas clearly
- One idea per paragraph
- Clearly state purpose

Sources: Taylor (1999); Johns Hopkins Medicine (2022)

Style

- Present clear sequence of events/ procedures
- Avoid irrelevant information
- Avoid legal jargon
- Write in conversational style
- Write in active voice

Source: Taylor (1999); Johns Hopkins Medicine (2022)

Style

- Be consistent with words and terminology
- Define technical or difficult words
- Know your audience
- Have forms reviewed by patient
- Use computer tools to assess readability

Source: Taylor (1999); Johns Hopkins Medicine (2022)

Format

- Use a readable type style (sans serif)
- Use 12-14 point type for text, 16-18 bold type for headings
- Use upper case and lower case for text
- Double spaced
- Space between sections
- Have 50/50 blend of white space and text

Source: Taylor (1999); Johns Hopkins Medicine (2022)

Format

- Use heading and advance organizers to introduce useful informational components (e.g. questions or declarative statements)
- Question/answer format
- Use lists whenever possible
- Use tables or boxes

Source: Taylor (1999); Johns Hopkins Medicine (2022)

Understanding

- Understanding is improved when patients or subjects must *verbalize information*, and
- Understanding is improved by administering quizzes and correcting inaccurate responses

Topic area	Question
Purpose	“If you were going to tell a friend what this study was about, what would you say?”
Procedures	“What are the main things you will do or will happen to you while you are in this study?”
Randomization	“Does everyone in this study have to do the same thing?” “Tell me in your own words how the researchers will decide whether you get the [intervention] or the [usual care]?”
Risks	“What are the risks, or bad things that might happen to you if or when you join this study?”
Benefits	“What are the benefits, or good things that might happen to you if or when you join this study?”
Voluntariness	“What will happen if you decide you don’t want to be in the study?” “What can happen if you decide to be in the study but later change your mind?”

Source: Kass et al (2014)

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