

Basics for Easy-to-Read Informed Consent Documents

The informed consent process is one of the most crucial components for human research protections. The process often involves a consent document, a copy of which is given to the patient/subject for their review and reference. However, in this day and age, it is not unheard of to have a 20+ page consent document!

How can researchers expect their patient/subjects to truly understand what is being presented to them? How can researchers help the people being asked to participate in studies comprehend the contents of the consent document(s)? It is not an easy task!

It is hoped that if you use the IRB's model consent form (contained in [IRB Full and Expedited Review applications](#)) and the below checklist as a guide for writing your consent document, your task will be made easier. More importantly, it is hoped that you will be protecting your patient/subject's rights and welfare by providing a fair and comprehensible written representation of the research in which they are being asked to participate.

Text

	Words are familiar to the reader. Any scientific, medical, or legal words are defined clearly.
	Words and terminology are consistent throughout the document.
	Sentences are short, simple, and direct.
	Line length is limited to 30-50 characters and spaces.
	Paragraphs are short. Convey one idea per paragraph.
	Verbs are in active voice (i.e., the subject is the doer of the act).
	Personal pronouns are used to increase personal identification.
	Each idea is clear and logically sequenced (according to audience logic).
	Important points are highlighted.
	Study purpose is presented early in the text.
	Titles, subtitles, and other headers help to clarify organization of text.
	Headers are simple and close to text.
	Underline, bold, or boxes (rather than all caps or italics) give emphasis.
	Layout balances white space with words and graphics.
	Left margins are justified. Right margins are ragged.
	Upper and lower case letters are used.
	Style of print is easy to read.
	Type size is at least 12 point.
	Readability analysis is done to determine reading level (should be sixth grade or lower).
	Avoid:
	Abbreviations and acronyms.
	Large blocks of print.
	Words containing more than three syllables (where possible).

Graphics

	Helpful in explaining the text.
	Easy to understand.
	Meaningful to the audience.

	Appropriately located; text and graphics together.
	Simple and uncluttered.
	Images reflect cultural context.
	Visuals have captions.
	Each visual is directly related to one message.
	Cues, such as circles or arrows, point out key information.
	Colors, when used, are appealing to the audience.
	Avoid graphics that won't reproduce well.

Source: National Cancer Institute, Bethesda, MD.

Informed Consent Process Tip: Give subjects time to think about the study! This will enable them to form questions, and the opportunity to obtain answers, which may influence their willingness to participate in the research.