

Comprehension in the Informed-Consent Process

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Using a generic consent form is desirable in the informed-consent process, but such forms may not give potential subjects an adequate understanding of a project. Attention to several aspects of design and content of the form will assist comprehension. A form matched to the knowledge and reading ability of the typical subject should be supplemented with verbal information for those who do not or cannot read the form properly.

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[Download template](#) (in rich-text format) for information and consent form.

Informed consent is an important part of a research project involving human subjects. The consent process is based on two fundamental ethical principles: protecting subjects (non-maleficence) and allowing potential subjects freedom of choice (autonomy). In a previous article at this site, we presented elements of an informed-consent document that help achieve these aims. Here we make suggestions aimed at improving a potential subject's understanding of the information and consent form, and we provide a generic (standardized) form.

Recent research has shown that a substantial proportion of consent documents do not cater adequately for subjects who have low reading levels. In a study examining information leaflets given to palliative care patients in Britain, only 40% of the population would have had enough understanding to give informed consent. Many of these documents did not meet basic guidelines on legibility and readability (Payne et al., 2000). In sport psychology, Cardinal et al. (1996) found that more than 85% of consent forms were at a reading level termed "difficult" or "very difficult". Here are some suggestions to improve readability of the informed-consent document...

- Type forms in a 12-point font.
- Don't justify the right-hand margin.
- Use short sentences and paragraphs.
- Don't use technical terms (jargon).
- Use the active rather than the passive voice.
- Use headings and bullet points.
- Adjust readability for intended subjects, especially those lacking higher education.
- Check readability statistics using the option in Microsoft Word or similar text editor.
- Pilot test the comprehension of the form.

Many institutional ethical review committees now provide generic informed-consent forms; see, for example, Thomas and Nelson (2001, p 420) and Olivier and Olivier (2001). A generic form is preferable to one constructed entirely by researchers, because...

- It helps researchers develop an understanding of ethical principles.
- It streamlines the ethical approval process.
- Subjects are likely to be better informed.
- Ethical principles, such as such as the right to withdraw, opportunity to ask questions, and statement of risks, are more likely to be dealt with, and therefore...
- Researchers and the institution may have more protection from litigation.

A generic form should be more comprehensible than one written entirely by researchers, but the researcher still needs to insert information on aims, procedures, risks, benefits, and safety unique to each project. This information might be hard for a subject to understand, so we still advise researchers to obtain readability statistics on the completed document and then to pilot test it.

When we added specific information to [our generic form](#), we obtained a Flesch Reading Ease score of 68.5. The higher the Reading Ease score, the easier it is to understand the document. For most standard documents, you should aim for a score of 60-70 (Flesch, 1948). Even so, reducing the reading level of an informed consent form may have little effect on a subject's ability to understand the document (Cardinal, 2000). Ideally you should pilot test the understanding on a sample of subjects representative of the intended study population. Input from a colleague in your department or in another discipline might also be helpful.

You should always give a verbal explanation about the project, for the benefit of those subjects with poor reading skills or a careless attitude to fine print. Providing the opportunity for subjects to ask questions and have them answered is also an obligatory part of the consent process

Remember that a comprehensible consent form alone does not protect a subject, other than by providing information on which to make a choice. The nature of the project—the research design, the procedures, and the ethical review process itself—must all be ethically acceptable.

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