Guidelines for Consent Forms and Information Sheets



General

Make the language you use as "lay" as possible. There is a very large distribution of reading skill levels in the normal adult population. Written information for participants should be pitched at around a 12-year-old reading level (Year 7).

Listed below are a number of examples of words that can be substituted for simpler terms:

Complex term	Simpler substitution
Analysed	tested
Trialing	testing
Examine	test
Proportion	how many
In the midst	during
Beneficial	useful or helpful
Effective	useful
per day	each day
venipuncture	blood test

Avoid long/multi clausal sentences, technical terms and jargon.

Avoid using different words (synonyms) for the same term, interchangeably. Pick one term, and stay consistent throughout the sheet. E.g. "Study drug", "Supplement", "medication", if these are all referring to the same substance, pick just one of these terms, and use it throughout.

An example of how to simplify a sentence:

Complex Sentence

"All new findings discovered during the course of this research that may reasonably influence your willingness to continue participation in this study will be made known to you as soon as they become available"

Overly complex words and terms are underlined.

Simpler version

"During the study, we may find results that could change your willingness to continue with the study. You will be told about any important results as soon as they are found".

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Reading Age and Readability

One helpful way to assess the linguistic complexity of your document is to assess its reading level. In a Word document follow these steps to determine the reading level of the document:

Go to: File - Options - Proofing - tick 'Check spelling with grammar' - tick 'Show readability statistics'

Then: Do a spell check on the document, once you have finished the spell check, the readability scores will appear with two figures:

Flesch Reading Ease

(0 to 100) High scores = more readable documents, aim for a document with a score of 60 or more.

Flesch-Kincaid Grade Level

This is based on USA reading grade levels, aim for a Grade Level score between seven and eight.

For example:

Two neuropsychology documents were run through this system. The first was a technical formal report (for the referring doctor and to go in the medical file) and the second was the client feedback sheet for the same patient (specifically for the patient for them to read and take home).

Neuropsychology Formal Report (for doctor):

Flesch Reading Ease - 28.8 Flesch-Kincaid Grade Level - 13.5

Neuropsychology Feedback Sheet (for client):

Flesch Reading Ease – 63.6 Flesch-Kincaid Grade Level – 8.4

This provides a good example of the large differences in readability that can occur in documents, even when they are based on the same set of information.

The actual Ethics Committee Research Proposal is likely to be technical and have lower reading ease scores and a high reading grade level rating. **However,** the patient information sheets and consent forms should have high Reading Ease scores and lower reading grade level ratings.