

Writing your PICF in Plain English

1. Background

For consent to be informed, it is important that researchers use language that can be easily understood by all prospective participants. The use of “Plain English” is the most effective way of explaining research to the general population.

Research has suggested that the average reading and comprehension age of adults is lower than what clinicians and researchers expect. The Oxford Guide to Plain English OUP: 3rd Edition (2009), states that the average reading age of adults in the UK and US is 13 years of age. The situation is likely to be similar in Australia. We must also consider our patients’ demographics, as a large proportion of hospital patients are aged 65 years and over and/or were born outside of Australia. Additional factors such as education, socioeconomic status and health literacy confound the difficulty in communicating often complex topics to ensure informed consent.

2. The purpose of the PICF

The purpose of the PICF is to provide information about the research project you wish to enrol a participant in. It assists in providing the potential participant with information on what the research involves, so they can decide if they wish to take part. In general, this includes **the purpose, methods, demands, risks and benefits, who to contact for questions/complaints and how to withdraw** from the research project.

The PICF must provide information that is:

- clear and concise
- in a format that participants are likely to understand
- from the viewpoint of the participant

The PICF is not a legal contract and therefore legal jargon should be avoided.

3. Basic Guidance

You should consider the demographics of the target audience and pitch your writing to this population group. For example:

- What is the expected age range of potential participants?
- What is their expected level of education?
- Are they likely to speak a language other than English?
- Will they have prior knowledge of the subject matter?

It is also important to have others read over the PICF to ensure it makes sense. Gaining input from a consumer (or consumer advisor) can be invaluable in structuring and wording your document properly. It is

also worth considering the way in which the document is formatted. There should be clear headings, margins and structure to the document to make reading simpler.

Below are some basic guides and a list of “Do’s and Don’ts” to help you ensure that the information you provide to prospective participants is clear, appropriate, and easy to understand:

DO...

- Use the templates provided
- Personalise the text (use we and you)
- Always refer to those who participate as “participants” not “subjects”
- Keep sentences short (up to 20 words) and keep paragraphs short and concise
- Use active verbs (i.e. use verbs ending in “ing”) when describing procedures
- Use everyday English whenever possible and correct grammar and punctuation
- Avoid medical jargon, abbreviations, acronyms
- Explain all medical terms in plain English, particularly when listing side effects of drugs
- If including percentages, include an explanation e.g. 10 % (1 in 10)
- List side effects under the headings Common (1 out of 10 or less chance), Less common (1 out of 11 to 1 out of 1000 chance) and Rare (more than a 1 out of 1000 chance)
- Where possible include sub-studies in the main PICF
- Number all pages using the ‘X of Y’ pagination option
- Use lists where appropriate. A list that is part of a continuous sentence has a semicolon (;) after each point and each point begins with a lower-case letter)
- Consider whether you wish to obtain consent for use of collected information and/or tissue in future research
- If including future research explain who will have access for future research, what testing is likely to be performed for what type of research, in what area of research
- If using translated PICFs, provide an English version, a translated version and a certificate of authenticity by a translating service to the HREC

DON’T...

- Do not include instructional information. This is given to the participant after consent at the appropriate appointment
- Do not use greater than or less than symbols (>,<), use words instead
- Do not include a place for initializing / signing the document on each page
- Do not use legal jargon
- Do not attach sponsor privacy statements to the PICF.
- Do not add extra clauses to the consent section. The statement “I agree to participant as described in this document” covers all aspects of consent
- Do not list procedures repetitively under visit headings.

- Instead state and explain procedures (where necessary) once and indicate how often or how many times the procedures will be done

4. Genetic Analysis and Genetic Testing Considerations

Genetic Analysis:

Additional information to be included in the case of genetic analysis:

- The nature of the testing e.g. pharmacogenetic / genomic, pharmacokinetic, biomarkers
- If the testing is optional or mandatory.
- Include a statement that explains that this analysis does not include genetic testing.

E.g. “The type of testing being done in this study is not testing that would result in information about a participant’s future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project.”

Genetic Testing:

Additional information to be included in the case of genetic testing:

Genetic Testing is testing that is intended to produce or could potentially yield information about an identifiable participant’s future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members.

It must be explained in the PICF that this is the intent or possibility of the genetic testing. The additional information should be provided as to the following:

- The nature of the testing and the research aim.
- If the testing is optional or mandatory.
- An explanation of what genes and DNA are.
- Include the names of any specifically targeted genes.
- The potential for the research to detect/generate information of social significance, e.g. non- paternity or non-maternity and that this information will not be disclosed.
- That genetic material or information may have uses unrelated to research and that this information will not be released for such uses, without consent, unless required by law.
- Information about any proposal to store genetic material and data for future as yet unspecified research.
- That if they do not consent to “future use” their samples and data will be disposed of once sample storage and record keeping requirements have been met.
- That they are free to withdraw from the research and request that their genetic material and data be disposed of (or if this is not possible, due to samples being made non-identifiable).

- The availability of counselling regarding the possible consequences of consenting to this use of genetic material.
- If relatives are also to be approached, the researcher will need the consent of the research participant to do this, and should provide information concerning the method of approach to relatives in the PICF.
- Whether participants will be advised of test results and whether the participant can choose not to be informed of the results. Additionally, include information regarding the possibility of information being provided to family members even if the participant does not wish to receive results (In the case where the testing may have health meaning for family members).
- Whether the results will be added to the participant's hospital medical records or stored separately.
- Information should also be provided about the procedures to be followed in response to a request for access (e.g. requests by a donor, relative, other researchers, insurer, employer) to stored genetic material, or related information generated by the research.
- If a genetic register is proposed, state that genetic registers will be established and conducted in accordance with the Guidelines for Genetic Registers and Associated Genetic Material (NHMRC, 1999).

5. Links and Resources explaining medical terminology in plain English

There are several websites that provide a glossary of plain English alternatives to medical jargon. Some useful ones include:

- [The Agency for Healthcare Research and Quality](#)
- [The National center for Health Marketing's Plain Language Thesaurus](#)
- [Center for Disease Control Plain Language Materials and Resources](#)

Other websites also provide assistance in writing in plain English, including:

- [The Australian Prevention Partnership Centre](#)
- [A guide on 'How to write in plain English'](#)
- [National Institute for Health and Care Research](#)