

# QUALITÉ

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## **PARTICIPANT INFORMATION SHEET READABILITY**

### **Developing a Readable Participant Information Sheet**

The Participant Information Sheet serves as a guide when describing to subjects all the necessary information they need in order to make an informed decision about participating in the study. Being medically-trained by profession, most investigators tend to use technical and scientific terms when constructing the participant information sheet. A participant information sheet containing technical and scientific jargons can hinder the subject's understanding and comprehension of what the research study actually entails. Subjects may not fully grasp the risks and benefits associated with the trial or research.

The Singapore Guideline for Good Clinical Practice (SGGCP) provides guidance on how the participant information sheet should be constructed. SGGCP 4.8.6 says that, "*The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.*"

The NHG DSRB SOP also specifies that, "*The information provided in the consent documents must be in a language understandable to the subject. The consent document should not include complex language that would not be understandable to subjects. Technical and scientific terms should be adequately explained using common or lay terminology.*"

In other words, the participant information sheet must be developed in such a way that it meets the literacy level of the study population.

#### **Literacy Level in Singapore**

Based on data from the 2010 Singapore Census, the literacy rate in Singapore is about 96% for population aged 15 years and above. About 68% of the population are educated beyond secondary school level, while 32% are educated up till primary school level.

Those aged between 25 to 39 years are the most highly educated, with 92% having secondary level education and above. On the other spectrum, about 70% of those aged 55 years and above, and 37% of those aged 45 to

55 years, have an education level that is below that of secondary school.

Some international research suggests that the readability of such documents should ideally be one to two standards below the reading literacy of the reader. In addition to developing a good participant information sheet, the investigator should also ensure that the information contained therein is properly explained to the subject in a manner that the subject is able to understand.

### **Making the Participant Information Sheet Simpler**

There are online medical dictionaries that investigators may use to translate medical and scientific terms into layman terms. A medical term such as “*hepatocellular carcinoma*” can be simply explained as “*a tumour of the liver*”. A good website that you may use is Mondofacto online medical dictionary

([www.mondofacto.com/dictionary](http://www.mondofacto.com/dictionary)).

In addition, there are free online software and websites that allow you to calculate or estimate the readability of your document. The *Flesch-Kincaid Grade* readability test is one such example. It is used to analyze and rate the readability of text based on the United States grade school level. The score is calculated based on an average number of syllables per word and words per sentence. A score of 8.0 would mean that the average eighth-grader will be able to understand the text.

Here are some websites that investigators may use to rate the readability of the participant information sheet:

- [www.onlineutility.org/english/reaability\\_test\\_and\\_improve.jsp](http://www.onlineutility.org/english/reaability_test_and_improve.jsp)
- [www.office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx](http://www.office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx)
- [www.harrymclaughlin.com/SMO.htm](http://www.harrymclaughlin.com/SMO.htm)

Investigators may also consider having a layperson review the consent document first to assess the readability and comprehensibility of the information to the target population.

### **Guidelines from National Institutes of Health**

The U.S. National Institutes of Health, Office of Human Subject Research provides a good guide on writing consent documents. Below are some questions that investigators should ask themselves when writing or reviewing a participant information sheet.

**Question 1:** Is the document written at a reading level understandable to research subjects?

**Question 2:** Is the document formatted well? Does it have headings which break the text into short sections?

**Question 3:** Can the document be shortened without compromising clarity or other requirements?

Usually, before a subject agrees to participate in a research study, he/she not only reads a written consent document but also discusses the study with a researcher. A suggestion when writing consent documents is to assume that prospective subjects will not talk to a researcher (or research nurse) at all about the study, and that all their information will come entirely from the consent document. If this approach is used, the document is more likely to be clear, complete, devoid of medical/scientific terminology and able to “stand alone”.

More information may be viewed at <http://ohsr.od.nih.gov/info/sheet6.html>.

#### **Resources:**

- i) NHG Investigator Manual - All That An Investigator Needs to Know
- ii) Participant Information Sheet Checklist (*Page 128 -131*) (*Available at the NHG Research Portal [www.research.nhg.com.sg](http://www.research.nhg.com.sg) -> Resources -> Research Online Guidebooks*)
- iii) NHG PCR SOP - 501-Co1 Informed Consent Document and Process Final. ([www.research.nhg.com.sg](http://www.research.nhg.com.sg)) -> Resources -> Research SOPs)

#### **References:**

- SGGCP – Section 4.8.6
- National Institutes of Health, Office of Human Subject Research (<http://ohsr.od.nih.gov/info/sheet6.html>)
- <http://www.singstat.gov.sg/stats/charts/lit-edu.html>