### **Consumer Plain Language Statement Review Guide**

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| When a person is asked to take part in a study, they are given a participant information sheet called a Plain Language Statement. This document should be as short and easy to read as possible but should also provide enough information to help the person decide whether or not to take part.  |

**What we would like you to do**

1. Read through the participant Plain Language Statement for the [XX] study that is provided with this document.
2. Add any comments, suggestions or revisions you might have.

Pages 2-3 of this document gives you a little more information about the study and some ‘questions to consider’ that may help when you review the Plain Language Statement.

**You can provide feedback/comments any way that you prefer. For example, you can:**

* Make changes directly in the electronic copy of the Participant Information Sheet using a different colour text to mark your changes, or, by using the “track changes” function.
* Make your own notes on a word document or piece of paper and send a copy back to us
* Write notes on a printed copy of the Participant Information Sheet and send a copy back to us

**Documents you will need**

* This document
* A copy of the draft Plain Language Statement and consent form for the [XX] study

**A few details about the trial you are reviewing**

[Notes for completion of this section - delete in final document

Provide information that will help the review.

For example:

- patient/healthy volunteer,

- age range

- inclusion/exclusion criteria

- patient at the point of diagnosis or several years post

- in what setting participants will receive the Participant Information Sheet e.g. community/health setting.

Are there any other special considerations e.g. if the participant would be receiving the information in limited disclosure consent situation (explain this in plain language to the person reading the information). Provide this information in a simple format using bullet points if possible.

You should also consider any flow charts or diagrams that might help to explain the trial.

Ensure plain language is used throughout. Please also amend the questions on the next page to suit your trial/study type.]

**Questions to consider to help you with the review**

**General questions to consider**

* Is the language used as simple as it could be? The information should be written in a way that is understood by someone in grade 8 (a 12 or 13-year-old)?
* Could fewer words be used to say the same thing in any section?
* Can you see any technical language that could be better described in ways a lay person would understand? Please note that medicine names cannot be changed.
* Could any of the words be changed to make the trial more appealing (or less scary) to participants?
* Does the layout (how the information is presented on the page) make it easy to read?
* Could diagrams/pictures be used in place of some of the text?
* Is the document engaging?

**Are the following points clear?**

* What the trial is trying to find out
* Why the trial is being done (why the research is important)
* What treatments (interventions) are being tested
* What is already known about these treatments, including the benefits and the risks
* How and when the person will receive the treatments
* What will happen during the trial (e.g. tests and procedures, number of trial visits)
* That the treatment will be free
* That treatments will not be chosen by the researcher but will be randomly allocated (by chance/ like flipping a coin)
* What will happen to the data collected and how the person’s privacy will be protected
* How the person’s treatment would differ inside and outside of the trial