NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Guidance on developing a Plain English Summary

To complement Participant Information Leaflets

2nd of February 2022

Version 1.0

Introduction

The Participant Information Leaflet (PIL) is an integral tool to support the informed consent process for research participants. However, providing written content in a clear yet comprehensive way can be challenging, especially when balancing accessibility of information and complex technical details associated with clinical trials. Furthermore, PILs can be lengthy and often contain 40 or more pages. While this level of detail may be necessary to ensure that research participants have all the information required to support their giving of informed consent, it can pose issues around transparency and comprehension of key information about the trial and create an additional burden on participants who may be ill, undergoing treatment, feeling worried about their health, or otherwise in a vulnerable position.

A Plain English Summary that provides a high-level overview of the clinical trial may help to reduce the burden on participants and facilitate their understanding of the salient points of the research. Information vital to support voluntary participation such as risks vs. benefits, potential changes in accessing standard of care, and pregnancy avoidance can also be clearly signposted from the outset. The Plain English Summary should typically be one to two pages in length and must complement (and not replace) the more detailed information provided in the PIL.

Developing a Plain English Summary

Consider the following actions when developing a Plain English Summary:

- Keep the summary to 1-2 pages
- Use size 12 Sans Serif font, 1.5. spacing and left aligned text
- No italics or underlined text
- Have a clear contrast between the text and the background, e.g., black text on white background
- Sentences should comprise a maximum of 15 words
- Keep paragraphs short and use headings to break up text where possible
- Avoid jargon and medical language where possible
- Tailor language to a reading age suitable for a 12 year old
- Define unavoidable medical language
- Use first person and second person pronouns where relevant, i.e., ‘I’, ‘you’
- Avoid language and tone that may be perceived as condescending or patronising

Section Headings

Examples of headings suitable for a Plain English Summary:

- Why?
  - What research question is being addressed?
  - What are the potential benefits to participants, patients, knowledge of the disease area, and the public?
- What?
  - Broadly what areas (disease, therapy, or service) are being studied?

  - What drug, device or procedure is being tested?
  - What tests or interventions will the participant have?
  - Will normal treatment / standard of care be impacted during or after taking part (e.g., withheld)?
  - What potential risks and adverse events are involved

- Who?
  - Who would be eligible?
- Where?
  - The sites where the study will be conducted.
- How, when?
  - How long will the study last; when will it start and end, number of visits?
  - Will the participant be reimbursed for expenses such as travel, time etc.?
  - Who to contact in the event of an emergency?

Additional Useful Resources

- The National Adult Literacy Agency's Plain English website provides a number of recommendations for developing Plain English Content: https://www.nala.ie/plain-english/
- The Health Research Authority's Guidance on PILs, see page 52: http://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf
- Test the readability of a document: https://readable.com/

Additional Useful References

- O'Sullivan L, Sukumar P, Crowley R, et al. Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis. BMJ Open 2020;10:e037994. doi:10.1136/bmjopen-2020-037994
- Baur C, Prue C. The CDC clear communication index is a new evidence-based tool to prepare and review health information. Health Promot Pract 2014;15:629–37.
- Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. 2nd edn. Philadelphia: Lippincott; Williams & Wilkins,1996: 96. 16M.
- Coleman E, O'Sullivan L, Crowley R , et al. Preparing accessible and understandable clinical research participant information leaflets and consent forms: a set of guidelines from an expert consensus conference. Research Involvement and Engagement (2021) 7:31. doi.org/10.1186/s40900-021-0026

Version Control

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