



Abstract Template

Project title What are the most effective strategies that can be used to ensure that clinical trial participant information leaflets are fit for purpose?

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Project details (max 250 words)

Participant Information leaflets (PIL) are commonly used to provide potential trial participants with details of the study purpose and conduct as part of the process of informed consent. There has been concern expressed that PIL's can be lengthy and complex documents that are not fit-for-purpose. Guidance from trial recruitment reviews (Trewick et al, 2018) identify the need for information to be clear, concise and jargon free, however guidance on the most effective process of development is lacking. Recent activity around performance based approaches to testing has seen improvements in readability of patient medication leaflets. There is no similar available consensus on 'user testing' of PIL's to ensure usefulness. There is a need to review the best strategies in relation to development and testing of PIL's to maximise their effectiveness in clinical trial conduct.

Aim: To conduct a scoping review exploring participant information leaflets use in clinical trials. Information around the content, presentation, sense, readability and testing of the instruments will be explored.

Methods: The scoping review will be based on the framework proposed by Peters et al (2015) informed by an original Methodological Framework for Conducting Scoping Studies devised by Arksey and O'Malley (2005), revised by Levac et al. (2010).

Outcome: This scoping review will provide an insight into common strategies used in the formulation and application of PIL in trials and their potential effectiveness. Information on strategies to maximise the effectiveness and readability of PIL can be used to inform the recruitment and informed consent process of clinical trials.

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