Participant information – an ethics committee view

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Abstract
The participant information sheet (PIS) is one of the documents that promote most discussion and concern for research ethics committees (REC). This article looks at ways to ensure the PIS meets their requirements based on the specific experience of a REC member. General problems include the fact that the PIS is too long, too complex, and written from the researcher's perspective rather than the participant's perspective. In addition, certain details are often lacking or unclear, the wording needs to be appropriate for the specific country and the benefit/risk balance should not be skewed in any way. Finally, every PIS should be proofread and tested on someone unconnected with the study. Following the advice given in this article will minimise requests for changes to the submitted PIS.

The UK Health Research Authority (HRA) is part of the National Health System (NHS) and was created to protect and promote the interests of patients and the public in health and social care research and to enable and support ethical research in the NHS. The Research Ethics Service is one of the core functions of the HRA. There are more than 80 research ethics committees (REC) across the UK. These RECs consist of between seven and 18 members who are a mix of experts (someone who is a registered healthcare or social work professional, or retired doctor) and lay members, and are entirely independent of research sponsors, funders, and the researchers themselves. This allows them to put the needs of research participants at the centre of their review. Their role is twofold:

- to protect the rights, safety, dignity, and well-being of research participants
- to facilitate and promote ethical research that is of potential benefit to participants, science, and society.

As a member of our local REC, I review a lot of research study applications and the documents that promote most discussion and concern are almost always those aimed at the study participants: the participant information sheet (PIS), consent form, and any direct recruitment documents. The information provided to study participants is crucial for a number of reasons. It explains to individuals everything that will happen to them, should they consent to participate, and it allows them to weigh up the risks and benefits of taking part so that they can give true "informed" consent. The aim of this article is to provide an insight into the issues that are seen by our REC in relation to the PIS, and to help applicants minimise possible problems in obtaining a favourable opinion from their REC.

Guidance from the HRA
The HRA provides very comprehensive and detailed guidance for researchers and ethics committees on the PIS and consent documentation.[1] This includes recommended content, design, and style for preparing an effective PIS and consent form and some very useful example documents, as well as a template with suggested subheadings. I strongly recommend readers consult this guidance before preparing these documents. I do not intend to repeat the guidance here but to concentrate on a few issues that are repeatedly seen by our REC. The HRA makes it very clear that this guidance should be considered as a framework, not a rigid template, and that one size will not fit all. Information requirements can vary greatly between different studies. For example, you do not need to produce the same detailed PIS and consent form to support a straightforward questionnaire study as you would to recruit into a complex drug trial.

Experience from the REC
Keep it simple
When patients are anxious or worried about their condition, treatment, or procedure, it is often difficult to retain information and therefore the documents need to be easy to understand and to the point. The HRA recommends a reading age of no more than 11-12 years. Those seen by the REC often use language that is far too complicated. Short, simple vocabulary and sentence structure should be used wherever possible. The REC will often request changes to ensure the document is understandable by prospective participants and written from their perspective rather than taken directly from the study protocol. We also recommend using simple pictures, charts, or diagrams showing what will be done and when. These are a very useful way of explaining what will happen in the study and are generally underused, however, the practice of direct transfer of the study schedule from the protocol into the PIS is not appropriate.

The view that the PIS is generally written at a level above the average literacy level of participants is supported by a study of 128 PISs carried out in 2019, which showed a mean Flesch Reading Ease score of 56.2 (SD 8.67), equivalent to a reading age of 16-17.[2] The study concluded that "patient information sheets are generally too complex for all patients to easily comprehend and researchers would benefit from clear national guidance from ethics' committees on writing patient information at a more appropriate level; participants would benefit from being provided with an easy-to-read research summary sheet". This is a consistent ongoing problem and, despite attempts to provide advice and guidance, it does not appear to have improved.

Keep it short
The PIS submitted for review by the REC is often far too long – sometimes approaching 35-40

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pages. In particular, parts of some sheets appear to have been taken over by company lawyers and include long complex sections relating to "liability" and "compensation". Whilst this information needs to be there, it should always be included as supporting information at the end of the document and kept to the minimum possible. For example, the PIS should not go into details of how a claim process will be carried out, only how it should be initiated.

Although the HRA suggests splitting lengthy sheets into three sections (introduction, what's involved, and supporting/further information), this advice is rarely followed. The REC will often request that researchers reduce the length by removing duplicate and unnecessary information and, if the length is still considered too high and cannot be reduced further, will suggest that supporting information be separated out for inclusion in a separate section at the end and that a half-page summary of the important points is included at the beginning of the PIS.

Involve the participants

The best way to write appropriate information for participants is to involve them in the creation of the information. It is often difficult for researchers to know what information is important to study for participants. For example: Can they eat and drink before their visit? How long is their visit likely to last? Involving them in the review of the documentation will help greatly. Currently, this is very rarely done and means that the documents provided to the REC are often written from the researcher's perspective rather than the patient's perspective.

Ensure appropriate content

Whilst every study is unique, there are certain things that the REC will always want to see fully explained:

- What is the study about?
- What will happen to the participant if they consent to take part?
- What side effects might develop?
- What limitations to their lifestyle will taking part impose?
- What payments (including for expenses) will be made?
- What will happen at the end of the participant's involvement in the research?

Some specific issues are regularly raised during REC review of participant information. In

particular, certain details are often lacking or need to be made clearer to the participants. These include which procedures are optional and which are a standard part of the study, as well as which procedures are part of standard treatment and which are additional procedures completed only as part of the study. This is particularly important when patients receive a lot of general testing or monitoring as part of their standard treatment for example in studies of patients with long-term chronic conditions. It must be clear what happens to blood and tissue samples at the end of the study. Will they be retained and if so where and what will be done with them? It must be clear what will happen to the data, is it personal data or anonymised data? Where will it go and who will have access to it? Information regarding how participants will be informed of the results of the study should also be included where appropriate.

The wording must be appropriate for the specific country. This is often a problem where a multi-national study has submitted a single, standard PIS to all countries. In the UK, for example, sections relating to the "cost of treatment" will normally not be appropriate as treatment will be provided under the NHS. Some specific words should be avoided, for example, patients are "invited" to take part rather than "chosen", studies are "reviewed" by the REC (and a favourable opinion given) not "approved".

The benefit/risk balance should not be skewed in any way. The benefits of taking part are often overstated and may unrealistically raise hope of successfully treating the disease, which could be seen as coercive. The discomfort, disadvantages, and risks of all study procedures and treatments must be clearly stated. The number of patients who have previously received the treatment and the number of adverse events reported by those patients should be given, in preference to the use of general terms such as "uncommon". Where the researchers are requesting potentially distressing information such as details of incontinence or previous miscarriage, the PIS should mention the potential for distress as an adverse outcome and how it will be dealt with. Sign-posting to relevant support and resources should be added to the PIS.

Studies that include different types of participants, e.g., patients and their care providers, or adolescent participants and their guardian, present a challenge when preparing a PIS. A single PIS for all participants often becomes confusing as their involvement in the study will be different in each case. For this reason, the use of a separate PIS for each type of participant is recommended.

Finally

Having followed the guidance from the HRA and taken into account the issues detailed above make sure you proofread the PIS for typographical errors and test it out on someone unconnected with the study. This way, you will minimise problems in obtaining a favourable opinion from your REC and will ensure participants fully understand what is being asked of them and can give true "informed" consent.

Disclaimers

The opinions expressed here are those of the author and not necessarily those of the Research Ethics Committee or the Health Research Agency.

Conflicts of interest

The authors declare that they have no conflicts of interest to report.

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Author information

Alison Rapley is a physiology and biochemistry graduate with over 35 years experience in the pharmaceutical industry, including over 22 within the medical writing group of a large clinical research organisation. She is a past President of EMWA and has been a member of her local Research Ethics Committee since July 2018.