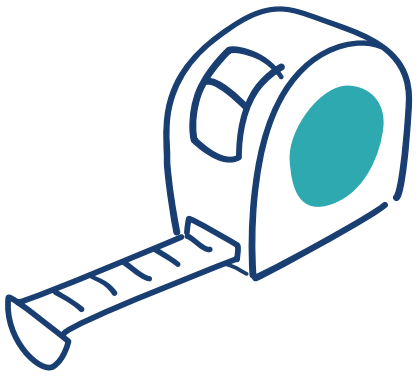
Patient Information Sheet Guidelines for researchers

Hello from GenerationR Young People's Advisory Groups for research members.

We believe that children and young people reading a patient information sheet (PIS) should not feel confused, uncertain, or scared about whether they wish to participate in a research trial or study. We have developed these guidelines, (alongside the associated PIS checklist) to help researchers make their PIS accessible, informative and reassuring.

Please take your time to read these guidelines carefully.

- All quotes are taken directly from feedback given by GenerationR Young People's Advisory Group (YPAG) members to researchers on their Patient Information Sheets and from our collaborative GenerationR workshop. These quotes, alongside our recommendations aim to support researchers with their PIS development.
- These guidelines should be considered a framework to follow as we acknowledge that one size does not fit all.



Structure of the document

First impressions matter

Length

Research has shown that the average attention span in the United Kingdom (UK) is 15 to 20 minutes. Start by asking yourself – would you expect a child or young person to read a PIS over five pages long?

> *"11 pages is way too much! It would definitely put me off reading all the way to the end."*

Structure of words and paragraphs

Make sure information is presented clearly and can help patients and their families to make an informed decision. If you use dense text, it may cause your audience to lose concentration or skip content altogether.

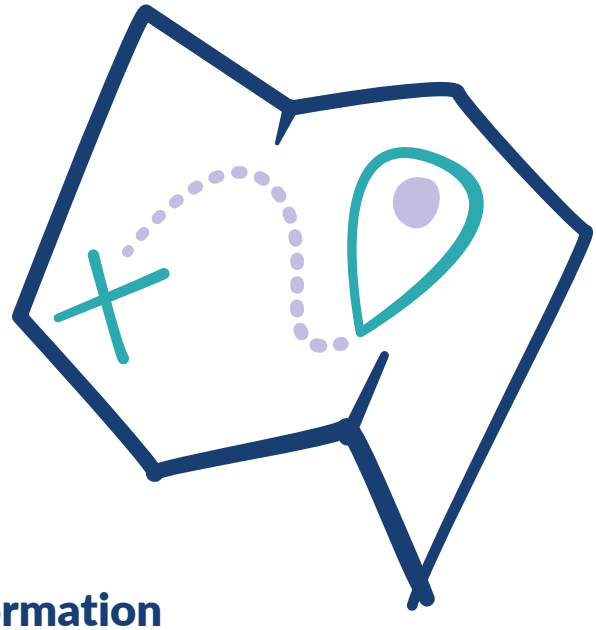
Top tips

- ✓ Use language that the general public is familiar with; avoid pasting information directly from the research protocol.
- ✓ Use the present tense.
- × Avoid writing in the third person; use 'I', 'we', 'you'.
- ✓ Pay attention to spelling and grammar; ask someone to check it for you.
- ✓ Keep sentences short and/or use bullet points where appropriate.
- ✓ Make sure information is not repeated.

Use the Hemingway App to make your writing clearer.

"Wordy paragraphs may make it too daunting to read. Patients might skip over important information they need to know that is buried in the text, especially if they were already stressed about being in the study."

"The paragraphs are very dense and blocky, maybe some of them could be split into smaller more manageable paragraphs or shortened."



Format of the document

Helping your reader to navigate the information

Use headings and sub-headings

A heading indicates the start of a section and can help your reader pick out the key information they need to understand the trial or study.

Top tips

- ✓ Use headings that are statements or questions to draw the reader in.
- ✓ A heading should be shorter than the information that follows.
- ✓ Leave 'white space' where possible.
- ✓ Use line spacing effectively. Try to condense the copy to make sure it fits on the final full page of the document.
- ✓ Use bullet points for lists.

Accessibility

Justified text can create gaps between words, which slows down reading particularly for people living with dyslexia.

Top tips

- ✓ Left align text, without justification. This makes it easier to find the start and finish of each line and ensures even spacing between words.
- ✓ Think about the font; its size, type and consistency:
  - Dyslexia-friendly sans serif fonts, such as Arial and Comic Sans aid readability as letters can appear less crowded.
  - As a rule of thumb, try to aim for font size 12-point. Font size 14-point is good for child readers whereas 16-point should be used for partially sighted people.
- ✓ Use **bold to highlight text** instead of italics, underlining or all capitals. (Using all capitals makes text harder to read and can look harsh. Italics or underlining make text harder to read).

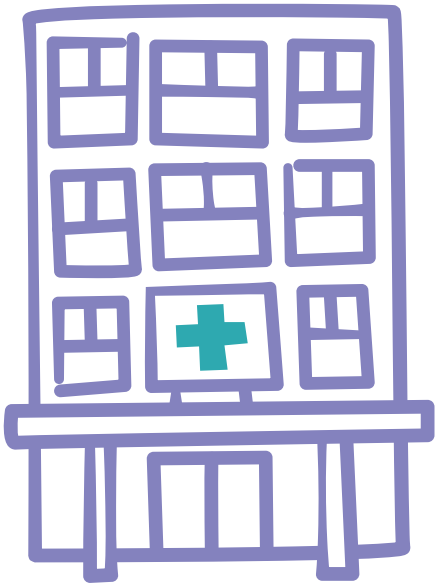
"The tables work really well when it's about frequency of clinic visits or what kind of tests are done in which visits but not if it's over two pages (makes it difficult to read!)"

Use multiple formats to present information.

- ✓ A timeline, flowchart or table can help break down the research and improve understanding.
- ✓ Other images (e.g., infographics or icons) can help explain the trial or study.

"The visit summary is good as it provides a clear step-by-step walk through of what drugs you will be given, and the blood taken from you."

"Don't assume all patients are experts on their condition."



Style of the document

Language and tone of voice

Plain English:

The average reading age in the UK is 9-11 years old. It's therefore important that the language used in a PIS is not a barrier to participation. Plain english is a way of writing and presenting so that a reader can understand and act on it after a single read. Remember; writing simple sentences does not always mean information is conveyed effectively. Simplify complex terminology using plain english explanations or everyday analogies.

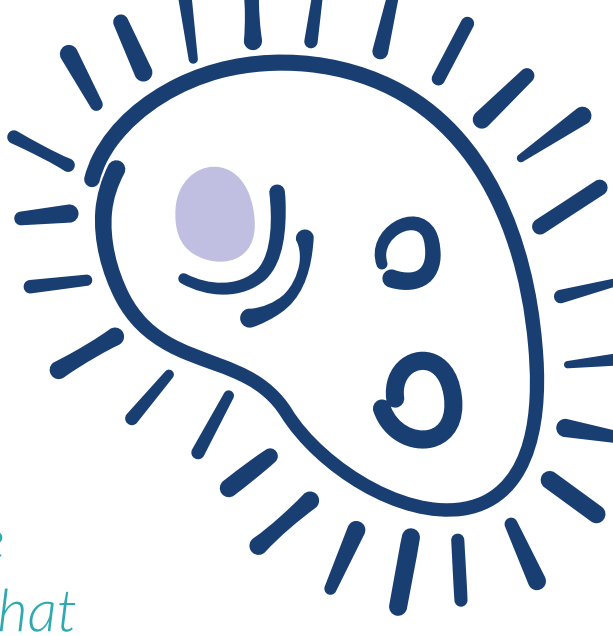
Visit the Plain English Campaign for more information.

> *"Reading abilities vary, make sure different ages of PIS are offered (some patients may have missed school because of their illness)."*

Top tips on choosing effective language

- ✓ Change medical jargon to non-technical words. Get creative and use simple translations where possible, but remember to provide an appropriate amount of detail.
- ✓ Use a 'glossary of terms' to provide explanations for complex words or acronyms.
- ✓ Ensure all acronyms are spelt out first before using their agreed abbreviation (e.g. Long Term Follow Up - LTFU).
- ✓ Ask a non-medical or young reader to check the readability of the information; they may be able to give some helpful suggestions.
- ✓ Gain the views of a Young Persons' Advisory Group (YPAG) for research. Note: this should only be sought having actioned the advice given in this document.

Visit mastering scientific language in scientific writing for more support.



"Explain the concept of cells as the younger children may not know what they are, so they may not understand the concept of stem cells properly. Also, explain what gene therapy is."

Top tips on finding the right tone of voice

Our *'tone of voice'* is the way our writing sounds, across everything we write.

- ✓ Think about the patient at the centre of your research; create a sense of relatability.
- ✓ Use the active voice to make sentences sound sharp and confident.
- ✓ Use personal pronouns such as 'I', 'we' and 'you', where possible as this is much warmer.
- ✓ Pose questions to draw your reader in.
- ✓ Think about what patients may worry about and seek to provide reassurance on:
  - Short and long-term physical side effects (e.g., are there any risks in taking frequent samples of bone marrow)
  - Needing emotional or mental health support.

"The PIS is quite impersonal and blunt. It might be good if it was a bit gentler and more conversational."

"The section on blood samples given and their use is slightly convoluted and confusing - so it could be good to reiterate that the study will monitor them and their health as a way of reassurance."

"Don't assume those who have been treated a long time don't still get scared."

"It is sometimes very hard (emotionally) to read about a trial due to all the possible side-effects mentioned but I know it's important that the children are aware of what they are signing up for."

Equality, Diversity and Inclusion (EDI)

‘Being seen and heard’

Top tips on making your PIS inclusive:

- ✓ Consider whether you need to have your PIS translated into different languages.
- ✓ Develop an easy-read version of your PIS to enable those with a learning disability to decide whether to take part.

  Think about the use of images and colour. Images and graphics should:

  - Support the meaning or concept behind the scientific words, be easy to understand and view.
  - Use captions to help explain complex ideas.
  - Be inclusive and not reinforce negative or stereotypical attitudes, particularly for ethnicity, age or gender.
  - Not be used solely for younger age PIS.
  - Remain clear if printed in black and white.

Take into account:

- ✓ Red green colour blindness is the most common form.
- ✓ Colour blind and low vision users may not be able to perceive the colour differences, and screen readers do not announce colours to non-sighted readers.

Learn more about colour blindness.

“Have copies ready that are an easier read for people with learning difficulties, ones with different colours of paper for people with dyslexia and with the first few letters of every word in bold for people with Attention Deficit Hyperactivity Disorder (ADHD).”

"A more inclusive use of words would be 'person of childbearing potential'. Make it clear that if someone got pregnant during the test, the subsequent response would place more importance on keeping the pregnant person healthy before the baby unless the pregnant person expressed otherwise."

"The PIS refers to "boys and girls" - change this to "young people"."

"Along with the PIS, I would prefer someone to talk me through this with my parent so it can be explained to me. Sometimes someone answering questions face to face would help to answer those questions I might not have thought of from just reading the PIS alone."

The Patient Information Sheet (PIS) – our recommendations

1. Study title

The title could be the same as that in the protocol or a simplified version which is understandable to a lay reader. If the latter, this should be used as the short title in the Integrated Research Application System (IRAS) form. The titles must be consistent throughout the PIS.

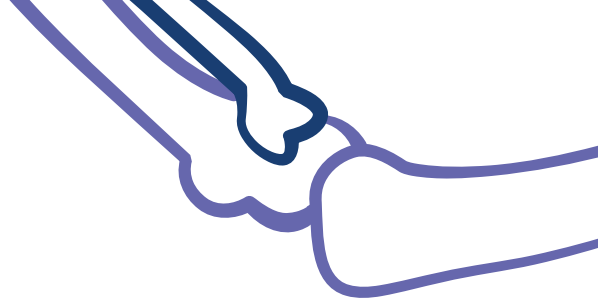
2. Study summary

The opening sentences are the most important and should explain what the trial or study is focused on. It needs to engage the lay reader from the start.

Use plain english to explain the health condition/illness which the research trial or study is conducting. Remember that complex health conditions or study protocols need an explanation for a non-expert reader. For more information, see Health Research Authority (HRA) advice.

Our suggestions

- Before you decide if you would like to join, it is important that you understand what the study is about, why it is being done and what it will involve for you.
- Please read this leaflet and think about it carefully. You may find it helpful to talk to your family, doctor or nurse about it for further advice.
- If something doesn't make sense or if you have questions, you can ask your parents/carers to give us a call and we can discuss it with you. We will listen carefully to any concerns you have, no matter how small.
- Please ask if there is anything that is not clear or if you would like more information. It is important that you take the time to decide whether the trial is right for you.



3. What is this trial/study about and why are we doing it?

Explain what a research trial/study is using terms appropriate for the readers age. Use plain english to provide a brief outline of the purpose of the research and the health condition/illness. Think about how your messaging will be received.

Our suggestions

- A research study is a way that doctors try and find out answers to questions to help children get better when they are sick.
- A research study looks to find out something new that could lead to changes to diagnosis, and to find better ways to prevent and treat disease.

Examples of explaining a condition:

Your body's blood cells are made in a "factory" in your bones called bone marrow. Bone marrow is a spongy material found in the centre of your bones. Inside your bone marrow are worker cells called stem cells. Their job is to make different blood cells. In Fanconi anaemia the bone marrow doesn't work properly so it doesn't make the blood cells in the right way. We are trying gene therapy to make all bone marrow work the way it is supposed to.

So, what is Gene therapy?

Gene therapy involves changing the genes inside your body's cells to try and treat or stop disease. Genes contain your DNA — the code that controls how your body works; from making you grow taller to controlling your body systems. Genes that don't work properly can cause disease.

4. Why have I been invited to take part?

Speak directly to the patient using a warm and friendly tone.

Our suggestions

- × Avoid saying 'your condition is difficult to treat', instead offer reassurance; 'this research is looking at ways to…'
- × Avoid saying 'you require the expert care of medical and therapy teams' as it is likely the patient is already aware and this will only add to their anxiety or worry.

5. Do I have to take part?

It must be clear that you are inviting potential patients to consider taking part in your research, but that it is entirely voluntary, and they can choose to stop at any time, without this affecting the care and treatment they are receiving.

Our suggestions

- Taking part in the research is voluntary. This means it is entirely up to you to decide whether to take part. If you agree to take part, we will ask you to sign a consent form, which means giving your permission. You will be given a copy of the information sheet and the signed consent form to keep.
- You are welcome to stop taking part in the research at any time, without giving a reason. This will not affect the standard of care you receive in any way.
- Remember, you can say yes now and change your mind later. It's totally up to you. You don't even need to give a reason if you no longer want to take part.

6. What will happen to me if I take part?

- Reassure the patient that only when consent or permission is given, will any procedures take place.
- When using a glossary of terms, make sure words are explained effectively using familiar everyday language.
- If there are multiple study visits required, describe each of them individually.
- The use of a clear table or flow chart outlining the timeline of events may help the patient to understand what is required of them.

7. What are the side effects, and will they happen to me?

- Be careful about being too direct when the PIS is aimed at young children who are likely to be worried and upset about their illness or condition. Instead, focus on providing reassurance.
- For older patients and teenagers with experience of being in hospital, try not to hide any of the facts or make your information appear too childish.

8. Will this study help me?

- Be transparent if potential patients may or may not benefit directly.
- If a patient is unlikely to benefit directly, ensure that they are aware that the outcome is unknown, which is the reason for conducting the research.
- × Avoid saying 'it won't benefit you directly'.

Our suggestions

- This research is not being done to improve your condition or health. We may, however, be able to find and possibly treat developing cancer or other long-term side effects.
- This research may not benefit you directly, but you may value the opportunity to participate knowing that by doing so you may be helping others in the future.

9. What will happen to the samples that I give?

State how samples will be used in the research (e.g., where they will be transferred or held, what analysis will take place) and in what form (e.g., anonymous, linked anonymous). Explain these terms using plain english and familiar analogies.

Our suggestions

- Anything we learn about you, will be kept private. We will use a code number instead of your name when your study doctor or nurse makes notes about how you are doing in the study.

10. What will happen to the results of the study?

You should inform all potential participants of your intentions to:

- Publish research findings.
- Present research findings at conferences.
- Feedback research findings to participants themselves.
- Provide participants with a summary or website link to access information.

11. Who has checked the trial or study is safe?

Ensure that the Research Ethics Committee (REC) has provided an explanation of their role. Provide the potential participant with reassurance.

Our suggestions

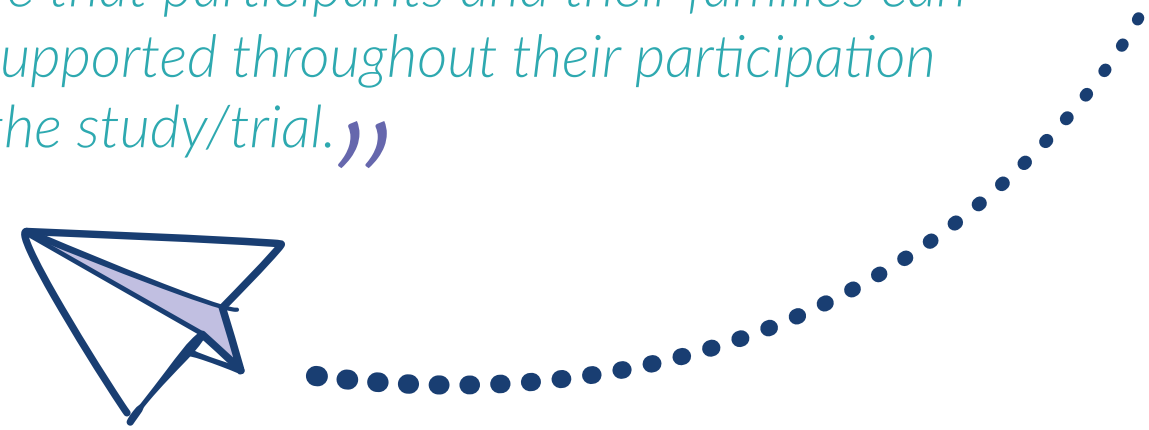
- The REC protects the rights and interests of the patients who will be in the research study/trial.
- All research in the National Health Service (NHS) is looked at by a group of people, called a REC. This is to protect the patient's safety, rights, wellbeing and dignity.

12. Where can I go for more information?

Can you signpost people to the following?

- Daytime and out of hours staff including photographs (if possible)
- Patient Advice and Liaison Service (PALS) for independent advice and the complaints team.
- Relevant charities and/or support groups.

"Providing a clear point of contact can help address any worries or uncertainties and ensure that participants and their families can feel supported throughout their participation into the study/trial."



What we hope patients and their families will think after researchers have implemented these guidelines

"The description of the trial has the right balance of scientific terminology combined with lay terms so the patient can be clear about what is going on. It isn't talking down to them and oversimplifying things, but it still explains it in a way that someone without scientific knowledge could understand it."

Co-produced by GenerationR Young People's Advisory Groups (YPAG's) members with reference to the Health Research Authority (HRA) Consent and Participant Information Sheet Guidance.

Learn more about GenerationR

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UK Standards for Public Involvement

WORKING TOGETHER
SUPPORT AND LEARNING

GenerationR
young people improving Research

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