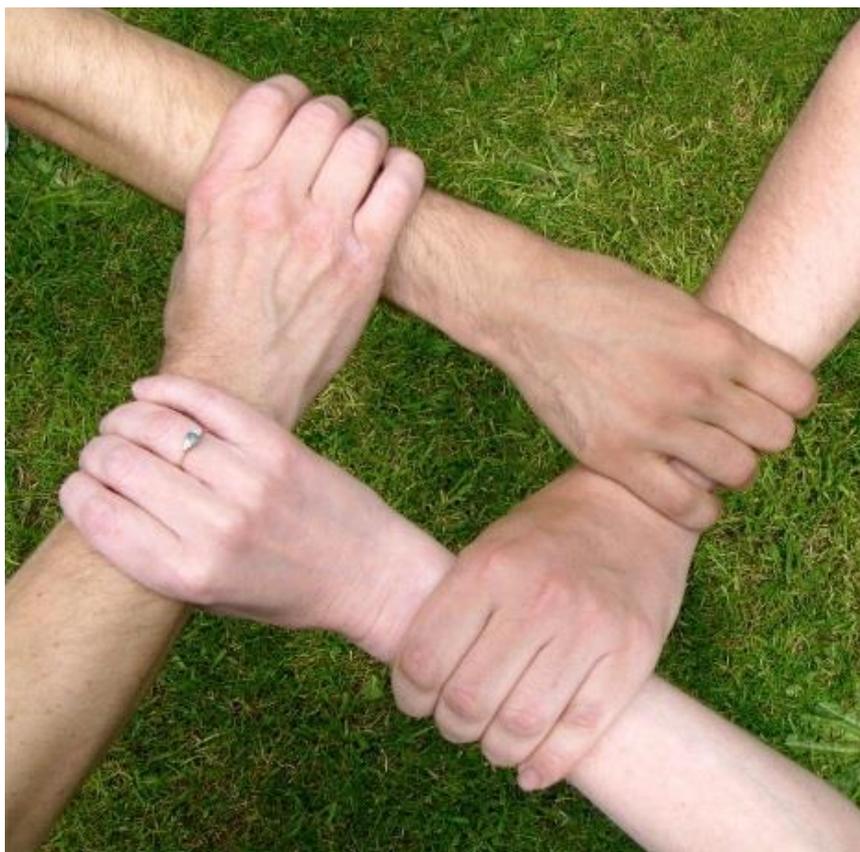


‘It Builds Trust’ – The Value of a Well Written PICF



As a researcher, you know that you need to write a Participant Information and Consent Form (PICF) so that you can start recruiting participants for your project. You're also aware that your ethics committee needs to approve your PICF before you can start using it. But did you know that **your PICF can play a role in making or breaking the success of your project?**

This information sheet tells you about the value of a well written PICF. It is based on interviews with researchers and other staff at The Royal Children's Hospital. It starts off by giving you tips on what makes for a well written PICF. It then talks about why your PICF is a key document in your project. Understanding why the PICF is so important to your project can give you the background knowledge – and the enthusiasm – you need to write a great PICF.

What makes a well written PICF?

Interviewees emphasised the importance of writing your PICF in **plain language**. They defined plain language as clear and concise writing that a layperson can understand the first time they read it. One person noted that the ability to “communicate your project in plain language is a skill that every researcher should have.”

A few people warned against using overly technical or formal language in your PICF. One person had this advice:

- Write your PICF in your own words. Write it the way you would explain it if you were talking to the person. I wouldn't write it as a scientist. – Allegra, researcher

Another person spoke about the need to **tailor your PICF to your audience**:

- Different audiences have different needs. Some groups might be across their illness and have a lot of information about it, others may not. Ask yourself: What do my audience need to know to make an informed decision? – Sam, Research Ethics and Governance employee

People also felt it was important to tailor the PICF template to suit your project. As part of this, they emphasised the need to **structure the information** in your PICF in a logical manner, and to use **relevant tables and visual aids**:

- You need to have your key information upfront. The order of information matters. Set it out logically and draw attention to the most important parts of the project. – Darlene, academic
- You have to cater for people who are visual, people who maybe aren't so great at reading. Pictures can really help the reader understand the information and make them engage with your PICF and, ultimately, with your project. – Quinn, researcher
- It's not just the text that's important, it's the visual presentation. We've moved past black and white forms. People these days are used to receiving colourful, snazzed-up information. – Allegra, researcher

Tables are fantastic. I've had so many families who've ripped out the table from the PICF and put it on the fridge. I always make sure that my tables are really clear and on one page so they are user-friendly. – Amy, research assistant

Using **short paragraphs and short sentences** was seen as important. In addition, one person noted that the way you format your PICF can increase – or detract from – reader engagement and comprehension:

- People don't like reading large chunks of information so I use lots of sub-headings and white space. – Quinn, researcher

People also talked about the importance of spending time simplifying, **editing** and revising their PICF:

- Editing is really important. I write my PICF and then try to make it shorter and shorter. I ask: Do I really need this information? Can I trim this sentence? How can I put this more simply? – Allegra, researcher

They also noted the role that **empathy** plays when writing your PICF. That is, as a researcher, you need to try to put yourself in the reader's shoes, and look at the PICF through their eyes:

- The main question I ask myself is this: Would I want to read it myself? If I, as a reader, find the document boring then I know something's wrong. – Allegra, researcher

Trust

A key word that came up in the interviews was 'trust'. People talked about how a well-written PICF facilitated participants' **trust in the researcher, in the project, and in the institutions** involved:

- A good PICF makes you as a researcher look good. It also reflects well on your institution. Conversely, a badly written PICF breaks trust. A participant won't have trust in you or your ability to do your job if you give them a poorly written PICF. – Sam, Research Ethics and Governance employee

In this sense, a good PICF was seen as a means to build positive relationships between researchers and participants:

- If you can give people clear and concise information from the outset then your relationship with families is better. A good PICF builds trust. It increases participant satisfaction with the research and lowers the possibility of complaints. – Amy, research assistant

Informed consent

A well written PICF was seen as “an integral part of the informed consent process”. One person noted that the PICF needs to be used along with a **meaningful conversation** between the researcher and the participant. They said that, while the PICF is targeted at the project’s participants as a whole, the one-on-one conversation gives the researcher the chance to gauge what an individual participant has understood about the project. Another person noted that, as a researcher, it is much easier for you to have this conversation with the participant if you have a well written PICF:

- It’s easier for me to talk to people about the study if I have a concise, visually appealing PICF. If it’s a long black and white form crammed with large sections of text, it makes it more difficult for me to have that conversation with the person. – Allegra, researcher

The PICF, along with the conversation with the participant, helps researchers make sure that **participants genuinely understand the project** before they take part in it:

- A good PICF means that people know that they’re getting into. What matters is whether that person is prepared to take on the risks involved with the project. It’s what matters to them. This is subjective: it differs from person to person. A good PICF helps the person make that assessment themselves. This is about autonomy and respect. – Darlene, academic

They added that if a participant is “not fully informed” about the project, “that’s when you’re likely to have problems in the future”:

- A bad consent form can have legal implications down the track. If it doesn’t give participants and families the information they need, in language they can understand, this can have repercussions. – Darlene, academic

In this sense, having a well-written PICF was seen as a **risk-management strategy** for researchers. This document can help facilitate a participant’s ongoing understanding of the project:

- A good PICF is something that the participant can refer back to. This helps them be clear about what the project involves. – Sam, Research Ethics and Governance employee

Ultimately, if participants receive information about the project in a way that they can understand, they are more likely to be “positive about the research”. In turn, this helps build and sustain good relationships between participants, families and the research team.

A good use of your time

Overall, people emphasised that, as a researcher, “it’s in your interest to **invest time in writing your PICF**”. They said that spending time writing the PICF “clarifies your thinking about the project”:

- It’s not until you start the process of writing your PICF that you really flesh out your project and learn what your gaps are. Having to write it all down in a way that participants can understand really tightens your thinking. If you can’t put it plainly for participants then you haven’t thought through it clearly enough. – Quinn, researcher

A good PICF can also be useful for the research team as a whole:

- A well written PICF can be a great tool for orienting new researchers to your project. – Priya, researcher

People also **warned against cutting corners** when it came to writing the PICF. They said:

- My advice to other researchers would be to invest time in your PICF. It’s one of the most important documents in your study. You use your PICF in all aspects of the study: recruitment, ethical practice, communication with participants and families, stakeholder engagement. So do it! Do the work. Utilise the support of the hospital’s Plain Language Adviser; they are a great resource. – Priya, researcher
- A good PICF will give you scope to be flexible in your approach, for example, by using your data in a different way in the future. So it’s good to spend time on your PICF – don’t rush it. Investing time in your PICF can future-proof it. It can mean that you don’t have to submit an ethics amendment down the track. – Sam, Research Ethics and Governance employee

Key messages

- A ‘good PICF’ is one that is written in **plain language**. It is concise, logically set-out and visually appealing. It gives participants enough information to be able to make an informed decision about taking part in the project.
- A good PICF can be a **powerful tool for recruitment**. It build participants’ trust in a researcher, their project, and in the researching institution.
- Given that the PICF is a **key document** your research project, it is important for you to invest the time in writing your PICF.