CT:IQ InFORMed Project

A report on consumer values and preferences regarding participant information sheets and consent forms

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1. INTRODUCTION

Ensuring the values and preferences of consumers are incorporated into the consent process and documentation

Australian Participant Information Sheets and Consent Forms (PICFs), especially those written for interventional research, are too long and written at a reading level beyond the capacity of most potential participants. Consequently:

- Participants may not fully understand the proposed research and the implications of participation.
- Research is less generalisable because the consent process may exclude populations for which consent is difficult to obtain.

The InFORMed project aims to provide a framework to support the development of concise, inclusive, participant-centred PICFs. Phase 1 of the Project culminated in the development of a simplified PICF template. This report describes Phase 2 of the project, the consumer testing and refinement of the PICF template.

The recommendations made in this report[1] and the principles underpinning the use of the template are derived from two sources:

- The consumer feedback from focus groups
- Evidence of best practice from a literature review conducted in 2022.

2. KEY FINDINGS FROM THE LITERATURE REVIEW

General findings

- People do not fully read documents that contain more than 1,000 words/4 pages of text [1]
- Consumer understanding is inversely proportional to the PICF's page count [2, 3]
- Long, legalistic PICFs can cause rather than prevent lawsuits [4]
- Legalistic PICFS may be harming participants and biasing trials through the 'nocebo effect' (negative placebo effect) [5-8]
- Multimedia can improve participant understanding and satisfaction [3, 9-12]
- Consumers have a role in determining the content of a PICF [13, 14]

Consumer perspectives

- Consumers prefer shorter forms for all study types [3, 15-19]
- Consumers are less interested in PICF content they consider as administrative [16, 20, 21]
- Consumers' information needs differ. Some want less information than provided, other more [20, 22]
- Consumers want the agency to decide the amount of information they read [23]
- Consumers want a balanced presentation of benefits and risks [23-25] in the PICF and do not want risks to be artificially inflated [26]

[1] The report is not intended to be a substitute for legal advice and should not be relied upon as such.

3. BACKGROUND

Long and complex PICFs

The InFORMed Project was initiated to develop a best-practice national PICF template for Australian health and medical research. PICFs have long been criticised for putting undue emphasis on the legal duty of disclosure*, rather than the ethical ideal for seeking consent [27, 28]. But despite their claim of completeness, PICFs often fail to provide information in a way that participants can use, which can negatively affect understanding and recall [2, 3, 15, 29-31].

***Note**: The emphasis on the legal duty of disclosure may not offer protection against lawsuits. In fact, in the US, a PICF has been the basis of legal action even in the absence of actual injury [4]. On the rare occasion that participants are harmed in trials, the comprehensibility of the PICF is likely to be one of the first study elements scrutinised [32].*

Very few researchers appear to be heeding NHMRC advice on the use of plain language, which recommends PICFs be written at a Grade 8 reading level or below. In a recent analysis of 248 Australian interventional PICFs, only 3 achieved this reading level [33]. PICFs, especially commercial PICFs for clinical trials, are typically lengthy. Table 1 illustrates the study's findings, which suggest many participants may not be able to read and understand PICFs fully.

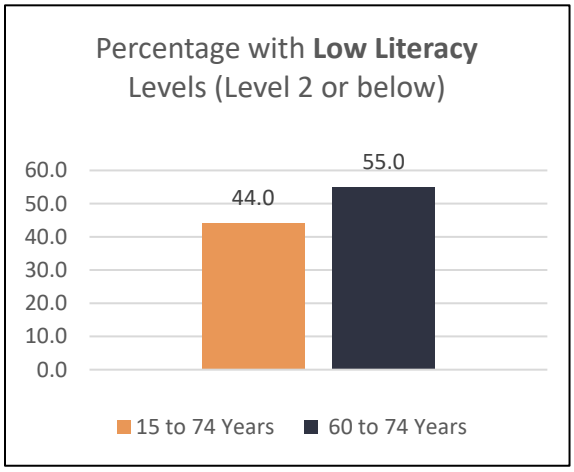
Table 1

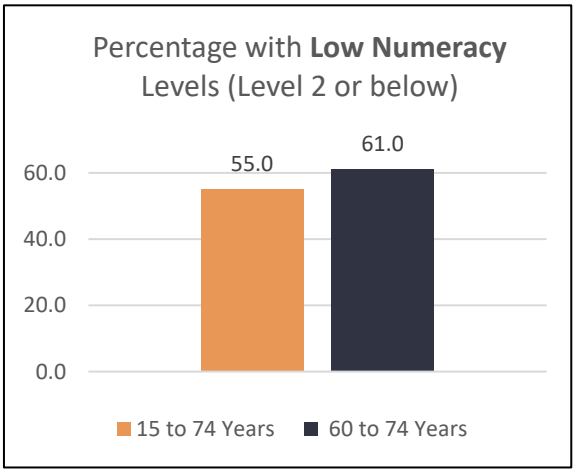
PICF with consent forms removed	Commercial (n=77)	Non-commercial (n=171)	Reading level
Number of pages	**18 (14-22)**	**7 (5-9)**	
Number of words	7826 (6720-9666)	3018 (1917- 4258)	
Flesch-Kincaid Grade Level	11.3 (0.9)	11.4 (1.1)	Late high school
SMOG	12.9 (0.7)	13.3 (1.0)	Tertiary level

SMOG - Simple Measure of Gobbledygook. Median (Interquartile Range) displayed for page/word counts. Mean (Standard Deviation) displayed for readability scores

Long and complex PICFs may be particularly challenging for older populations [25, 34] and participants with low education or literacy [2, 35]. Literacy and numeracy are categorised into 5 levels [36]. Adults with literacy levels of 2 or less do not have literacy skills to meet the demands of daily life. Adults with numeracy levels of 2 or less, may struggle if mathematical concepts such as probability are not clear or visual [37, 38]. **Figure 1** illustrates the proportion of Australians with low literacy and low numeracy skills in the 15-74 age group compared with the older end of that age group.

Figure 1





Australian Bureau of Statistics [39]

3.1 What information should be present in the PICF?

For consent to research, the National Statement requires potential participants to have an adequate understanding of the *purpose, methods, demands, risks and potential benefits of the research*, and where applicable, the *alternatives* to study participation [40]. For research involving a treatment or intervention, the disclosure requirements for research consent reflect the common law[2] requirements for consent to medical treatment. Since 1992, legal disclosure requirements in Australia are based on the standard set out in *Rogers v Whitaker* (1992) 175 CLR 479, being what a reasonable person[3] would be likely to attach significance in making medical care choices [28]. Consent to treatment requires disclosure of the *nature and purpose* of treatment [41, 42], any *material risks* [43, 44] any *benefits*, and *reasonable alternatives* [43, 44].

When research is conducted in the treatment setting, potential participants must also be informed of the *dual purpose* of research – providing treatment and deriving generalisable new knowledge [45]. They must also understand how their treatment and experiences in the research setting differ from usual care including how their confidentiality may be affected [45]. **Figure 2** illustrates the key elements for disclosure for research consent.

For an adequate understanding of research, the consent process should be based on good communication that facilitates shared decision-making [27, 28]. The exact nature of what a person needs to understand depends on several factors including how a study affects the person's interests [46]. International trial regulation aligns closely with Figure 2.

[2] Case law made by judges.
[3] A hypothetical person used by lawyers to represent an average person

Figure 2: Consent to Research

[1] Including the voluntary nature of the research

[2] Dual purpose – Clinical care & research

[3] How the research alters the participants healthcare experience.

3.2 Do the outputs from this project align with the National Statement?

The National Statement promotes a flexible approach to consent. For example, Chapter 2.2 requires that information be presented '*in ways that are suitable to each participant'.* What constitutes sufficient information for informed decision-making '*depends on the nature of the project*' [40]. Indeed, the National Statement does not mandate the use of a PICF. Section 2.2.5 promotes flexibility in the way consent is obtained: *'Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent)'* [40].

This project aims to better utilise the flexibility in the National Statement. It also aligns with the current thinking of the NHMRC, which is to support initiatives that promote risk-proportionate and flexible approaches to research that reduce the burden on both the research community and participants [40].

3.3 Do outputs from this project align with Good Clinical Practice?

The layered consent approach to information provision described on page 7 allows sponsors to provide participants with all the elements of consent listed in Section 4.8.10 of ICH GCP. This information can be in the PICF or shared between the PICF and any supplementary information[4] provided in a separate layer.

Note: Full compliance with ICH GCP is not a legal requirement in most countries, including Australia. The *Therapeutic Goods Regulations 1990* (Cth) only apply to unapproved therapeutic goods trials. Even for these trials, the TGA's annotations to ICH GCP state, *"If requirements specified in the National Statement appear to differ from those specified in the Guideline for Good Clinical Practice, the TGA recommends compliance with the National Statement" [47].*

[4] Information that is considered less/not relevant to decision-making when participants consider a study.

4. LAYERED CONSENT

One intervention identified from the literature review already used to simplify consent is *layered consent* [23]. Its basis is that PICFs for health research often contain two types of content:

Key Information: disclosure of sufficient information that a reasonable person would expect to receive for any decision to participate in a study.

Separate Supplementary Information*: information considered useful by some, but for others, may obscure the content most helpful for decision-making.

While some people will seek out an in-depth understanding of all aspects of a study as part of their decision-making, others will not want to be burdened with detail. As one expert explains - the challenge is that researchers cannot predict what each participant wants to know [48]. Layered consent therefore provides the ability to tailor consent to the different needs of potential participants.

Layered consent departs from usual practice in two ways:

- The physical separation of the key and supplementary information*.
- Potential participants can sign the PICF without reading the supplementary information. They have control over the amount of information they read.

***** Supplementary information can either be additional detail about content in the PICF or new content. The PICF should clearly outline the supplementary information available, which should be easy to access.

In the UK and Australia, layered consent has been used to simplify PICFs for low risk, pragmatic trials [23, 49]. However, there is less evidence of its acceptability in studies with higher risk levels. The user testing phase of the InFORMed project was conducted to determine whether consumers and study teams supported the concept of layered consent in a broader range of study types.

5. DEMONSTRATION PROJECTS & FOCUS GROUPS

The user-testing phase was designed around three forthcoming studies. These demonstration projects are described in **Table 1**. For each, a consumer focus group was held to test the study's draft PICF, which was developed using the InFORMed template. The draft PICFs were co-developed by members of the InFORMed Working Group and the study team for each demonstration project.

Participants with lived experience of the disease or topic being researched were selected (n=40). Recruitment was primarily through a commercial panel to help ensure the groups were representative of the Australian population (age, sex, ethnicity, and education).

Table 1: Demonstration Projects

Group #	Sponsor	Type of Study	PICF Length
1	The Australian Kidney Trials Network (AKTN)	A repurposed drug trial	8 pages
2	BIOTRONIK Australia Pty Ltd	A premarket devices trial	7 pages
3	Orygen (Youth Mental Health)	A 10-minute online survey	3 pages

* The InFORMed PICFs for the trials were considerably shorter than the PICFs provided by the study group.

Three consumer focus groups were held in December 2022 as part of a qualitative research study. The study was approved by Monash Health Ethics Committee. The focus groups were conducted to:

1) Test the draft template developed by the project team to see if it works in a range of studies.
2) Confirm whether layered consent is supported by consumers in studies with different risk levels and complexity.
3) Help refine the content, structure, and tone of the PICFs for each demonstration project by confirming:
   - Whether each PICF contained sufficient information to make a decision about study entry.
   - Whether the language and wording were appropriate.
   - Whether the presentation/layout of the PICF was supported, including the use of bullet points, tables, images, diagrams.
4) Obtain detailed feedback on the wording in the privacy section of the PICFs relating to data and sample storage, data linkage, genetic testing, and data sharing for future studies.

6. KEY FOCUS GROUP FINDINGS

Overall, participants were very complementary about the InFORMed template PICFs appreciating their brevity:

- *I was given a booklet of 24 pages [before surgery] …but this is perfect. It gives you everything you need to know, and you can read this in less than 10 minutes so it's perfect. (BIOT)*
- *[The PICF] was probably the most concise I've read… I had enough information…I am assuming it wasn't written by an academic? (ORY)*

LAYERED CONSENT

Participants in all focus groups supported the concept of layered consent, primarily because it enabled an individualised approach to consent that met their different information needs:

- *…the option to choose is great as some people like a lot more information up front and others don't. (BIOT)*
- *It caters to both sorts of people [those with low or high information needs]. (BIOT)*
- *It would be helpful for learning about the main points to understand initially and then obtaining more detail if required. (AKTN)*

One person was concerned about the legality of layered consent. Many were familiar with the concept of separation of information, drawing comparisons with everyday life where the terms and conditions may or may not be read:

- *It's not a bad idea as long as legally defensible. (AKTN)*
- *I think having the second layer…it's like the terms and conditions. (AKTN)*

SUFFICIENT INFORMATION

Participants in all groups felt that the PICF contained sufficient information to make a decision to participate:

- *I think there was plenty of information. About the amount of information, I would look for. (ORY)*

Some felt there was more information than necessary:

- *[The PICF] is a lot to absorb and that's coming from someone who's memorised four languages. (BIOT)*
- *…for me, it's probably more information than I need [privacy section]. (AKTN)*
- *…for a 10-minute survey, I mean, I would expect to read instructions maybe one or two minutes maximum I would say. [ORY)*

The group familiar with trials suggested extra content that was present in PICFs they had seen. However, it was not always clear whether the extra content was expected in the PICF or the 2nd layer:

- *…something like complaints or compensation section which are in other studies. (AKTN)*
- *…It doesn't explain the hypothesis of the action of [study drug]. (AKTN)*

INCLUSIVITY

Some participants in all groups raised the need for the consent process to support the inclusion of diverse and underserved groups, potentially through the provision of online and/or multimedia information:

- *…quite a few people may not even be up to that, reading the basic layer. Would it be possible to have a YouTube link where someone reads out about that or speaks it? (AKTN)*
- *…video will probably be 90% better than reading the whole booklet… everybody's capable of following video and understanding it. (BIOT)*

Others cautioned some groups may be unable or unwilling to interact with technology:

- *… also provide a hard copy of the extra information if someone requests it, as some groups of people might not be comfortable using QR codes and technology. (AKTN)*
- *…a lot of older people or under-privileged people can't use the internet or don't have access to a device, so they need a paper printout. (AKTN)*

Consumers were asked about the concept of long PICFs. Some felt long PICFs may exclude people by discouraging participation:

- *…you'd just give up before you start. (ORY)*
- *I think that some people might look at that and then they assume the survey itself is as complex as the form that they see. (ORY)*
- *…some people might tune out and then just choose not to consent. (BIOT)*

PROPORTIONALITY AND FLEXIBILITY

Participants indicated that they expected variation in PICFs for different study types, and advised that the PICF they were provided satisfied this expectation:

- *The content and language seem to be appropriate for the kind of study. (AKTN)*
- *…given the low risk of the clinical trial or study, I think it had enough information. (BIOT)*

While most participants felt the tone was right, some participants requested that wording and tone be tailored to their preferences:

- *It [the PICF] is a little patronising. (AKTN)*
- *…adjust the tone in a way that sounds more empathetic. (ORY)*

Some participants in the two clinical trial groups suggested using a design with an upfront summary:

- *…one of the information sheets that I received that I liked the most… was like a booklet and then it also said for each dot point, if you want more information, you can find it on this page. (BIOT)*
- *So, I kind of liked the idea that if everything important is on the first page. (BIOT)*
- *I think it could be useful having a summary page. (AKTN)*
- *If you need an answer to a particular question, you just go to the index. (BIOT)*

PRESENTATION AND LAYOUT

Participants liked the way the PICFs were presented:

- *I liked the way it was set out… easier to read, not just blocks of text…plenty of white space. (ORY)*
- *I thought it was really clear. (BIOT)*
- *I thought the layout was really good and it was easy to read. (AKTN)*

Participants supported the inclusion of visual content:

- *I like the idea of visuals I'm not so much a reader, but I like visual. (BIOT)*
- *I prefer the graphics. We live in a very visual society. (ORY)*
- *Yeah, personally, I think it's great, the photos, all of it. (BIOT)*

The majority supported the use of bullets:

- *I love dot point bullets it makes everything so simple and clear and easier to understand. (AKTN)*
- *…blocks of text are too hard to read. Bullet points are much easier to read. (ORY)*

Tables were also supported, particularly for display of risk statistics:

- *…it was a really good sheet…especially that table around the side effects and how it's grouped into three. (AKTN)*

Many participants liked the icons in the test PICFs, but views on whether they informed the content were mixed:

- *The icons are really good, they stand out what you are looking at. (BIOT)*
- *I like the icons. I don't think they inform but they just add to the layout. (ORY)*
- *I think the icons break up the text; they don't inform or distract. (AKTN)*

However, others considered them confusing:

- *I actually don't see the need for them. Just reading it, you know, to look at the icons on the side there, to me, it just doesn't make sense. (BIOT)*
- *I'm looking at them I'm thinking, was that a male, female, two females? That's distracting for me personally. (BIOT)*

In addition to the Participant Information Sheet, participants in the Orygen focus group were shown a version of this information displayed as 1-page bulleted list. Several were comfortable with this version, preferring its brevity, either as a separate document or integrated into the survey:

- *It's readable. It's clear. And I do a lot of surveys, and this just looks like one I would go straight into. I like the format. (ORY)*
- *…definitely, it is a lot easier and clearer to read than the three-pager. (ORY)*
- *I love how concise it is. (ORY)*

PRESENTATION OF BENEFITS AND RISKS

The desire to contribute to science was considered a factor in a person's decision to enter a study. Participants felt that PICFs should be written to emphasise this benefit:

- *…there's a fair bit of information on what the risks of taking part are, but there's not much on page 3 about the possible benefits of taking part. (AKTN)*
- *[Add]…something like you will help Australians dealing with body image issues. (ORY)*

When asked about the consequences of long PICFs, several participants felt they overinflate the perception of risk:

- *I think if you have a lot of information as well, it can be fear inducing…they might think it's higher risk than what you're making out… (BIOT)*

PRIVACY AND DATA SECURITY

The InFORMed team developed a concise version of privacy wording written in plain language that was considered to meet the requirements of the *Privacy Act 1988* (Cth). This was adapted as appropriate for each study:

- The AKTN study contained a comprehensive privacy section including data use and storage, data linkage and data sharing of de-identified data and samples for future research.
- The BIOTRONIK study included the use and storage of data.
- The Orygen study included data use and storage and data sharing for future research.

Consumers advised that the privacy content in the BIOTRONIK and Orygen PICFs was appropriate (less than half a page). The content of the privacy section in the AKTN PICF was considered appropriate by some, but others felt the detail could be in the second layer:

- *'The privacy and security stuff is fine by me'. (AKTN)*
- *I think most of the information currently provided in the document is critical; and probably a minimum in the first layer. (AKTN)*
- *To tell you the truth, I'd probably skip over most of it. (AKTN)*

- *I think having the 2nd layer probably be more useful. Because like I said, it's like the terms and conditions. (AKTN)*
- *I can actually see that being less in this layer 1, and click on this for more information. (AKTN)*
- *…[if] it's the same as every other trial, maybe putting it in the 2nd section? (AKTN)*

Participants in the AKTN group felt it was especially important to ensure clarity and precision in the privacy section:

- *…throughout it says 'we', and I don't know who 'we' are...'we' needs to be clarified. (AKTN)*
- *I just wondered if it's appropriate to put a sentence…this will not be used to analyse your DNA. (AKTN)*
- *I think the timeframe for use of samples or information should be a definite, not an approximate. (AKTN)*

There was also a lack of understanding of privacy terms and concepts, such as data sharing:

- *You need to share your data in order for the study to ultimately be successful in the end as without them checking all data they have nothing to compare against. (AKTN)*

Some participants clearly wanted to have a say on who had access to their data:

- *It [sharing for any future research] seemed a little bit too open ended for me. (AKTN)*
- *It might be something that they're going to study that I might be ethically against…(AKTN)*

Others were not concerned about data sharing:

- *…if you are a research participant… you are usually pretty happy [to share data]. (BIOT)*
- *…I think it's overkill a little bit. I think if you agree to do the research…probably consenting is enough to actually disclose and release information? (ORY)*
- *… if you didn't want anything shared, you wouldn't be agreeing to do the research. (ORY)*
- *…any future research, that's fine. (AKTN)*

Some participant wanted a more granular level of control when their information is shared for future use:

- *…you gotta be careful when you share out there, if this is strictly related to the pacemaker, why not… but not my personal health details or anything else? (BIOT)*
- *I would be happy to have the samples stored but would like my permission sought for each future research study. (AKTN)*

The recent data breaches were raised by all three groups, which prompted some to request reassurance about security. Others were more fatalistic about their data:

- *Given recent cyber hacks of Optus and Medibank, should more assurance be provided as to online security? (AKTN)*
- *…if the 'powers that be' want to take the information from anywhere, they'll just do it anyway. (ORY)*
- *…anyone can get hacked these days, so it doesn't really matter. (BIOT)*

7. GENERAL RECOMMENDATIONS

The following recommendations arise from the focus group findings and literature review.

Adopt layered consent

Layered consent was strongly supported in all focus groups because it promoted autonomy by giving participants control over the information they read during the consent process.
This finding is consistent with recent Australian and US studies [16, 21, 23], which suggested consumers were comfortable with the removal of supplementary information from the PICF to avoid overwhelm. Focus group participants also felt that layered consent could have a direct impact on the likelihood that they would read and understand PICFs by making them more concise. The risk level of the study did not appear to affect support for layered consent.

If layered consent is proposed for a study, the reviewing ethics committee should confirm that participants have easy access to any supplementary information.

Actions

- Seek further advice on layered consent to determine whether there is a need for a checkbox on the consent form to confirm participant awareness of access to supplementary information.
- Engage with industry to determine whether further assurance is required (and from what source) before layered consent for higher risk studies is adopted.
- Engage with HRECs to create awareness of layered consent.

Promote flexibility and proportionality in PICF development

The InFORMed project User Guide should promote flexibility and proportionality in the development of PICFs.

Flexibility
The PICF template developed by the InFORMed Working Group should provide a *starting point* for the development of concise, easy-to-understand PICFs**.** It should not be considered a one-size-fits-all template by researchers or ethics committees. Researchers should be encouraged to *think critically* about the information that most likely supports participant decision-making and only use this information to create their PICFs. For complex, higher risk studies, PICFs should be kept concise by providing some of the detail in a separate layer. Not all the content in the template will be relevant for every study.

Both participants and demonstration project study team members confirmed the template very valuable as the basis for PICF development, but flexibility to adapt it is required to enable researchers to respond to consumer feedback. For example, the suggestion by some participants in both clinical trial focus groups led the AKTN and BIOTRONIK study teams to opt for the inclusion of a summary page (Appendix 1).
Similarly, support for the use of illustrations and visuals in the BIOTRONIK focus group, coupled with feedback from the study team that ethics committees often request graphical representation of study schedules, led to the development of an example timeline graphic (Appendix 2).

In some studies, a PICF may not be needed. Feedback from participants in the social science study supported flexibility in the way information about a study is presented. Although some researchers may prefer a separate PICF, others may wish to integrate the wording into the survey or questionnaire. UK guidance takes a flexible approach and similar wording could be adopted in Australia.

> *'For postal/online surveys or self-administered questionnaire-based research, it is not necessary to include a separate Participant Information Sheet or consent form. Participants should still be provided with sufficient information to enable them to reach an informed decision whether to complete and return the survey/questionnaire or not, but this may be included as a short introductory paragraph as part of the survey/questionnaire itself or included in a short covering letter.*
>
> *Provided that the information adequately describes in broad terms the nature and purpose of the research, why they are being invited to take part, how the information collected will be used and stored, and how the findings might be made available to them, then completion and return of the survey/questionnaire will indicate consent on behalf of the participant. Where the research involves sensitive questions and/or potentially greater threats to participant confidentiality then this should be clearly spelt out in the covering letter to participants…'*
>
> UK Health Research Authority

Action: Confirm with the NHMRC whether the above wording is acceptable for the InFORMed Project User Guide.

Proportionality
Proportionality is particularly relevant to risk disclosure. Excessive risk disclosure in interventional trials is known to cause the *nocebo effect* (the opposite of the placebo effect). It occurs when excessive information about adverse events leads participants to *expect* and *experience* them. This can lead to

poor adherence, drop out, and increased anxiety [26, 27]. The nocebo effect can bias studies by distorting estimates of treatment effect [28, 29].

The InFORMed focus groups and other studies suggest that participants want a balanced presentation of risks and benefits in PICFs that support decision-making. They do not want risks to be inflated in order to mitigate institutional risk [26].

All groups felt the information in the risk section of the PICFs was explained in sufficient detail, however two of the groups felt the benefits were underplayed or missing and suggested they should be highlighted.

Action: Ensure the template and user guide promote a balanced representation of a study's risks and benefits.

Provide access to best practice guidance to optimise the content, structure, and tone of PICFs and to make them more inclusive

Systematic reviews [50, 51] highlight evidence-based interventions that improve participants' understanding of PICFs, such as writing at a Grade 8 reading level, using graphics, and improving their layout to ensure high processability. Participants in the focus groups mentioned all these factors. Regarding content, the Australian Commission on Safety and Quality in Healthcare (ACSQH) suggests healthcare organisations take a 'universal precautions' approach to health literacy [52], which is equally applicable to health research. This approach is based on the following premise:

- Everyone benefits from clear information.
- It is difficult to identify which potential participants may be at risk of misunderstanding.
- An individual's health literacy can vary. Anxiety due to a diagnosis or illness can reduce the ability to process information.

Optimisation strategies should be combined [15]:

- Reducing PICF length by including *only* information that is *just* sufficient for decision-making.
- Following best practice guidance for writing in plain language, such as guidance published by ACSQH [52] and Australian Government [36].
- Using images, graphics, bullet points and adequate font size to improve processibility [15, 17, 19, 35, 53]

Action: Ensure the InFORMed User Guide links to best practice resources to support the development of well designed, well written PICFs.

The way in which PICFs are designed can unintentionally exclude populations that are usually underserved by research [54, 55], which in turn affects the external validity of trials. Participants in the focus groups recognised this and proposed measures to make PICFs more accessible to a broader range of the population such as:

- Creating a video/narrated version of the PICF that is easily accessible.
- Ensuring multimedia content has subtitles translated into various languages.

Action: Provide guidance for researchers on methods to create low-cost video/audio versions [5] of their PICF that participants can access easily (e.g., preloaded i-pad for in-patients, QR codes on paper PICFs or hyperlinks.)

Action: Ensure the InFORMed User Guide recommends the production of 'back-up' paper copies of PICFs/supplementary information for participants who do not want to interact with technology.

Action: Consider developing/signposting to guidance to encourage researchers to create adapted versions of their PICFs to enable greater inclusion of underserved groups, such as those with impaired vision [56] or dyslexia [53].

Encourage user-testing to ensure PICFs contain sufficient information for decision-making and meet participants' needs.

The inclusion of consumer values and preferences in PICFs not only makes them more ethically defensible [57], but can also improve recruitment [58]. These are reasons enough to encourage researchers to invest the time and resources needed for consumer involvement when developing their PICFs. For clinical trials, it is also an excellent example of how the National Clinical Trials Governance Framework could be operationalised.

Simple, concise PICFs should be a goal for all research, regardless of whether layered consent is used. This requires the removal of redundant information. Consumers can advise whether the information contained in a PICF is sufficient for informed decision-making. They can also identify confusing wording. The method of involvement can range from informal discussions or interviews with consumers to more formal discussion groups.[6]

8. RECOMMENDATIONS: PRIVACY SECTION

Simplify wording to Grade 8 reading level

The wording in the privacy section was generally considered much improved by those familiar with the typical wording in standard PICFs. However, it should be simplified further to a Grade 8 reading level.

For studies with more complex privacy arrangements, provide some of the detail in a separate layer

The demonstration projects contained varying amounts of privacy information. The Orygen and BIOTRONIK focus groups contained a limited privacy section (< ½ page) and their focus groups participants were happy with the proposed content being retained in the PICF. By contrast, the AKTN focus group (privacy section > 1 page) were more supportive of the information being layered, so that

[5] Applications such as Loom can help researchers develop a simple, low-cost video versions of their PICFs.
[6] Appendix 3 and 4 contain sample pre-reading and moderator guide for a consumer discussion group.

reading the detail was optional. This finding aligns with other qualitative research on patient perspectives where privacy information was considered less relevant than other types of content [21, 24, 59].

Another argument for the layering of privacy information relates to the consequences of excessive disclosure of confidentiality information. Evidence from social science studies suggests that excessive disclosure has negative consequences, such as apprehension and reduced confidence that confidentiality will be maintained. It can also discourage people from participating in research because they assume the questions they would be asked are personal or threatening [60]. At least one study also suggests that participants support a layered approach to presenting privacy information [10].

As outlined above, layered consent could be adopted for all studies if appropriate safeguards are in place to confirm that participants truly have access to the supplementary information.

Action: Adopt a layered approach. Provide guidance on the privacy content suitable for the PICF and the separate layer.

Action: Seek advice to determine whether there is a need for a checkbox on the consent form to confirm participant awareness of access to supplementary privacy information.

Improve 1) public awareness of data sharing and 2) public awareness of the risk minimisation strategies used to protect privacy by linking to educational content

Data sharing

Data sharing holds great promise for improving healthcare. The sharing of individual participant data (IPD) increases study transparency by enabling independent scrutiny and analytical reproducibility. It also supports IPD meta-analysis, which allows more granular and complex analyses such as subpopulation analyses to improve the evidence based for medicine [61, 62]. However, the concept of data sharing is not well understood [62, 63], and there is a lack of awareness of its importance among the wider research community and the public [62-65]. This lack of understanding and awareness is seen by the public as a barrier to data sharing [66]. Information provided as part of the consent process offers an opportunity to raise awareness of data and sample sharing, as well as data linkage.

Public consultations suggest that there is widespread support for data sharing, but that this support is conditional for the sharing of both data and human tissue [63, 65, 66]. Similar findings are reported from Australian research that explores public views on genomic data storage and sharing [67]. Public dialogue confirms the 'red lines' for data sharing, namely, the public does not support data sharing with insurance and pharmaceutical companies. However, the findings from a UK public dialogue exercise [65] suggest that when the role of pharmaceutical companies is explained, the public are more supportive. In another study, the majority supported the use by for-profit companies when framed in the context of the potential for the development of treatments for patient benefit [68]. There is also support for data linkage when patient benefit is likely [63].

Risk minimisation strategies

Risk-minimisation is a prerequisite for data sharing and de-identification is considered a key measure to protect privacy [63, 66]. As identified in the focus groups, people want to know more about how and with whom their data are shared. They also want transparency about the process, and to know what

safeguards are in place [63]. However, significant amounts of privacy content in the PICF is likely to cause overwhelm, and therefore educational content should be included in the supplementary information.

Action: Create educational videos on topics such as risk minimisation strategies (including de-identification), the value of data/data sharing and data linkage. Examples are provided in Table 2. This content will improve transparency and public awareness of how data is used and could be used by researchers as a second layer of information to supplement the privacy information in their PICF.

Table 2

De-identifying data	Information for the public on patient data use | UCLH Biomedical Research Centre (nihr.ac.uk)
Value of data /data sharing	https://youtu.be/fJ2hyXCOOyQ
Biobanking	https://www.mcri.edu.au/research/projects/childrens-cancer-centre-biobank
Data Linkage	https://www.menzies.utas.edu.au/research/research-centres/data-linkage-unit/what-is-data-linkage

Clarify when separate consent is not required for data sharing to support consistency in PICF requirements across Australia

Australian research suggests there is confusion over privacy terminology and recommends succinct definitions of terms like de-identification, and further guidance on how researchers can ensure study data is suitably de-identified [62]. Therefore, researchers and the ethics community should be better informed about the circumstances when consent is required and when it is not. This will support consistency in PICF requirements across Australia. In fact, this information is already present in Australian government guidance [69]. This guidance confirms that when data has undergone an appropriate and robust de-identification process, it is not personal information, and therefore not subject to Australian privacy laws. It also confirms that the risk of re-identification does not have to be removed entirely. Instead, those sharing or releasing data must reduce the risk of re-identification until it is very low. In other words, if there is a *reasonable likelihood* of re-identification, data is not considered de-identified and consent would be required [69].

In every focus group, participants were acutely aware that de-identification measures are not foolproof, however, it may be prudent to articulate this in the PICF wording.

Action: Amend the wording in the PICF to describe the concept of 'reasonably de-identified' information.

Although separate consent is not required for the use of robustly de-identified data/samples, for research transparency to maintain public trust in research participants should be made aware that their de-identified data will be shared for the public good, especially for data/sample sharing for future use. [66]. As a result, international regulation (e.g., from the UK and US) suggests that PICFs clarify whether de-identified data and tissue will be shared for future use rather than asking for individual consent. The

US Common Rule, for example, requires researchers to add one of the following statements to their PICF:

> *(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.*
> *Or*
> *(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.*

Action: Inform participants rather than seeking their consent for sharing robustly de-identified data and amend the template to take out the requirement for options for the level of sharing**.** Encourage researchers to link to video(s) describing the importance of data sharing and the methods used to ensure security**.**

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11. APPENDIX 1: EXAMPLE SUMMARY PAGE (AKTN)

PARTICIPANT INFORMATION AND CONSENT FORM

AUSTRALASIAN KIDNEY TRIALS NETWORK

Full Name of Study	Implementation of metformin therapy to ease decline of kidney function in Polycystic Kidney Disease (PKD)
Principal Investigator	Professor Andrew Mallet

If you prefer to watch a video explaining the study, please scan this QR Code:

Invitation to take part

- We invite you to take part in a research study because you have Autosomal Dominant Polycystic Kidney Disease (ADPKD).
- Please read this information carefully. Discuss it with relatives or friends, and your doctor if you wish.
- You do not have to take part. This will not affect your care in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Feel free to ask us if anything is unclear, or if you would like more information.
- If you decide to take part, we will ask you to sign a consent form. We will give you a copy to take home.

Key Points

- We want to find a better way to treat **ADPKD**
- We want to see if a drug called Metformin slows the growth of cysts in the kidney.
- This study compares Metformin with a 'placebo', an inactive pill.
- Metformin is currently widely used to treat diabetes.
- The study is in 2 parts:
  - A 'run-in' phase lasting 3 months
  - The main study lasting 2 years

Contents

How to contact us

If you have any questions about this study, please talk to:

Doctor: Dr Kimberley Jones

Phone: 03 6666 8888

Research Nurse: Michael Lee

Phone: 03 3333 5555

Adapted from Knapp et al 2009 [70]

12. APPENDIX 2: EXAMPLE TIMELINE ILLUSTRATION (BIOTRONIK)

3. What do I have to do if I take part?

The study lasts for 12 months. We will read and adjust your pacemaker when needed, and collect information from your CardioMessenger. When the study is finished, your pacemaker doctor will continue to see you as usual. The pacemaker will be left in place to manage your heart condition

VISIT 1 **Date:**

Enrolment

If you decide to take part, we will ask you to:

- Sign the Consent Form at the end of this document
- Complete a short questionnaire about your quality of life.

VISIT 2 **Date:**

Implantation - We will:

- Take an ECG and implant a new pacemaker.

Hospital discharge - We will:

- Check your pacemaker is working properly
- Take a chest x-ray
- Take an ECG
- Give you the CardioMessenger and show you how it works
- Give you a card to carry that lists your type of pacemaker and who to ring if you have issues with your CardioMessenger.

VISIT 3 and 4 **Date:**

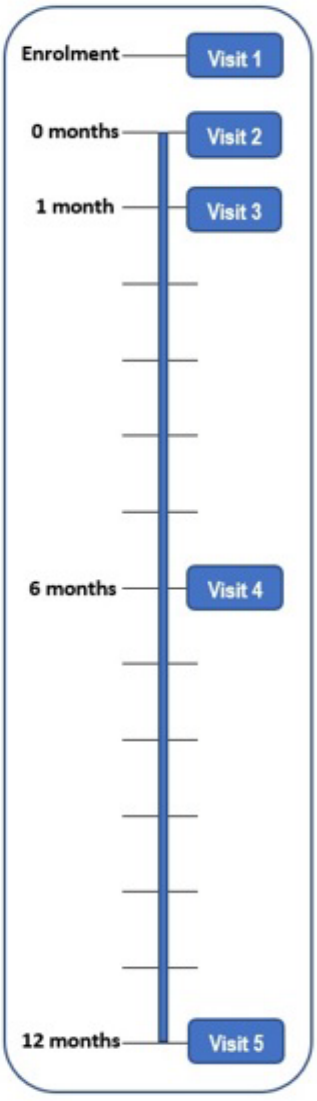
At the 1-month and 6-month hospital visits we will:

- Check your pacemaker is working properly
- Take an ECG.

VISIT 5 **Date:**

At the 12-month visit we will:

- Check your pacemaker is working properly
- Take an ECG
- Take an echocardiogram if your doctor thinks you need it
- Ask you to complete a short questionnaire about your quality of life.



After the study ends, your doctor and the pacemaker clinic will continue to monitor you as normal. The table below explains the procedures you will have.

Adapted from Knapp et al [70]

13. APPENDIX 3: EXAMPLE DISCUSSION GROUP PRE-READING

SAMPLE PRE-READING LETTER FOR THE DISCUSSION GROUP

Thank you for agreeing to attend this discussion group. This document gives you more information. If you have any questions before the meeting or find you can no longer attend, please contact [insert relevant contact information]

What topic will be discussed?

- People give their 'informed consent' before taking part in a research study.
- Before people take part in a study, they are given a Participant Information Sheet.
- This document provides the information that will help them decide whether to take part.
- People also use the Participant Information Sheet to talk to their family or friends and to ask the study team questions.

Why we want your feedback.

- Participant Information Sheets written by scientists are often very long and complex.
- This makes it hard for some people to understand what the study is about and why they have been asked to take part.
- As a person or carer with experience of [disease/condition], you have unique and valuable insights into what it may be like to be approached to take part in a study. As such, we would value your opinion on the Participant Information Sheet for a study we are planning.
- We have included a simplified version of a Participant Information Sheet for this study, which is called [XX study]
- Please read it before the discussion group. We will ask your views about it at this meeting.

Feel free to contact [Study Team**] if you have any questions:** Email/phone.

Attach draft PICF and discussion group details and add other information about the focus group as relevant.

14. APPENDIX 4: EXAMPLE MODERATOR GUIDE

SAMPLE MODERATOR'S GUIDE

WELCOME AND GROUND RULES

We have invited you to take part in this discussion group because you a familiar with [disease or condition]. We will use your feedback to improve the information given to participants for [Study].

- My role is to guide the discussion today.
- There are no right or wrong answers, only opinions.
- Please feel free to share your ideas and opinions, even if they differ from what others have said. It's helpful to hear different points of view.
- We'd like to hear from all of you equally.
- Please be respectful of others' privacy.
- Because we have limited time together, I may jump in and move the discussion forward.
- Please turn off any mobile phones or other electronic devices until we are finished.

[If applicable, confirm consent for recording].

PARTICIPANT WARM-UP: *Introductions/icebreaker*

PURPOSE OF THE GROUP:

- We are holding this discussion group to hear your thoughts on the information given to people when they are approached to take part in a study. We call this document a Participant Information and Consent form – or PICF for short.
- We want to make the PICF for this study as simple and easy to understand as possible. If it is too long and complex, some people will not be able to read or fully understand it.

IF A SECOND LAYER IS PLANNED:

- We are all different. Some people like a lot of information before making decisions, others only want the key information.
- One way to cater for everyone is to only include the key information in the PICF and link to/provide extra information [on our study website/in another leaflet/as an optional appendix etc.] for people who want it.

[Provide an overview of the study and other relevant information such as the requirement for ethics review. Read/summarise the Participant Information Sheet.]

SAMPLE QUESTIONS

- Do you think this information sheet contains enough information to make a decision to take part in the study? If not, what should be added?
- Do you think there is too much information and if so, how could be make it simpler?
- Do you think the language/wording could be simplified further?
    - Are any sections confusing?
    - Are there any technical/medical terms? Have they been explained so that people will understand them?
- Is this document too formal/informal?
- What are your thoughts on the layout and presentation?
    - What would help improve the layout?
    - What would make this document easier to read or understand?

SAMPLE QUESTION IF A SECOND LAYER IS PLANNED

To make this information sheet simpler or easier to read, could some of the detail be moved to our website/separate leaflet/appendix? Is there any other information you would like us to add in this layer? [e.g., information about the disease condition].

PROMPTS: As necessary.

WRAP UP: Final thoughts and thanks.