



InFORMed

Redesigning Consent to Research

Consumer & Stakeholder Survey Findings on Participant Information and Consent Forms (PICFs)

CT:IQ initiated the InFORMed project, working with consumers and other stakeholders to redesign and simplify PICFs in order to help consumers make more informed decisions about participating in research. Two separate surveys were administered to consumers and stakeholders exploring similar themes. The survey insights below support the need for change.*

LENGTH

"The key is making it simple to read and keep it as short as possible"

92%

Consumers agreed it is important to make PICFs 'much shorter'



88%

Stakeholders agreed that PICFs are 'too long'

"... simplify it but not losing the priority of conveying enough information ..."



LAYOUT & NAVIGATION



97% Consumers

agreed it is important to 'improve the design and layout'



85% Stakeholders

agreed that PICFs are 'too hard for participants to navigate and find information'

"Formatting could be more visually appealing and engaging."

CONTRACTUAL

90%

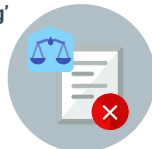
agreed it is important to make PICFs 'feel less like a legal document'

Consumers

Stakeholders

65%

agreed that PICFs have 'too much legal wording' and 'too much privacy wording'



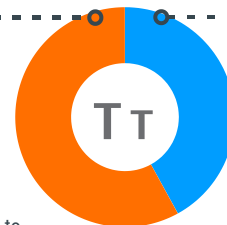
"The PICF should NOT be USED as a legal document... pull out the essential facts that a reasonable person would want to know to make a decision ..."

TEXT DENSITY



87% Consumers

agreed it is important to 'use visual aids to increase understanding and comprehension'



63% Stakeholders

agreed that PICFs are 'repetitive' and 'include unnecessary information'

"Too wordy, too cumbersome, needs to be in plain language.."

LANGUAGE

94%

Consumers

agreed it is important to simplify the language to make PICFs 'easier to understand'



50%

Stakeholders

agreed that PICFs contain 'too much medical jargon'

"It was difficult for the average (non-medically trained) person to understand and felt very impersonal."

UNDERSTANDABLE INFORMATION

89%

Consumers

agreed it is important to provide 'only the key information upfront and an attached appendix or links if the participant wants more information'



62%

Stakeholders

agreed that PICFs are 'focused on disclosing information rather than improving understanding of the information being provided'

"I want to see the key information – the benefits and the risks (but not pages and pages of side effects)..."

*Consumers who agreed it was very important/somewhat important to the question "If we could make PICFs more focused on needs of participants, how important are the following changes to you"
*Stakeholders who strongly agreed/agreed to the question "To what extent do you agree with the following perceived PICF issues"



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Project Summary

- ✓ Participant Information & Consent Forms (PICFs) are often long, complex and not consumer focused.
- ✓ Nine out of 10 consumers agreed these forms need a significant overhaul to be simple, straightforward, and more consumer friendly.
- ✓ The CT:IQ initiated InFORMed project is working with consumers and other stakeholders to develop a new national PICF to support consumers to make more informed decisions about participating in research.
- ✓ In October 2021, two national surveys were conducted, one with consumers and one with other stakeholders, to identify the issues with current PICFs and explore areas for improvement.

Survey Respondents



Consumers: 157 complete responses

93 had participated in research (56% clinical trials, 39% in social science/ behavioural research), most aged 35-70 years, English speaking, located across Australia, in metro and regional areas



Other Stakeholders: 558 complete responses

275 researchers/sites, 110 investigator initiated/academic researchers, 95 ethics and governance, 62 sponsors/contract research organisations, 16 other

All respondents agreed that the consumer voice is the most important in this conversation about PICFs.

The surveys received ethics approval from Swinburne University Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018).

Check out the project:



CT:IQ
Clinical Trials:
Thinking Smarter