Talk, read and write:
A three tiered Participant Information and Consent Form

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Good Practice Process (due 2016):
Currently piloting in 16 clinical trial sites across 7 states and territories:

> One aim of the process is: Implement National standard PICF template

1. Melbourne Health
2. Monash Health
3. Barwon Health
4. Peninsula Health
5. Royal Children’s Hospital Melbourne
6. St Vincent’s Hospital Melbourne
Ethics

1. Research merit and integrity
2. Beneficence
3. Justice
4. Respect
The participant information and consent form has three parts:

**General information**
The booklet (Part A) introduces the participant to clinical trials. It guides them through the informed consent process and provides some questions to ask the clinical trial team.

**Trial details**
An information sheet with details about a specific trial, including its purpose, duration, required procedures, risks and any potential benefits. This guidance document is design to enable researchers to develop their own PICF.

**Consent form**
A form delivered with Part B that individuals, parent/guardian’s or a person responsible, sign if they wish to participate in a trial, to show that they voluntarily agree to take part and understand what their involvement will be.
Part A
General information

• Clinical Trials
• Who has reviewed and approved the trial?
• Clinical trials and you  \( A+B+C \)
• Informed consent
• What will happen to information about me?
• Can I leave a trial
• Asking questions
• The clinical trial team


Part B
Trial details

- Word template
- Question and answer format
- Purpose of the specific trial
- Procedures and demands
- Risks and the potential benefits
- Study, site and HREC contacts

Part C
Consent form

• Word template
• Standardised
  • User guide
• Separate withdrawal form
• Separate witness section form

Supporting Resources: User Guide

Number of pages

Kincaid score: 11.2 → 8.0

Modified formatting

Three tiered PICF framework
PICF User Guide

NationalPICF.com.au/research.html

Participant Information and Consent Form
Guidance and NHMRC Standard Clauses

Compensation
Pregnancy
Ionising radiation
MRI scans
Psychological distress
Chemotherapy
Use of illegal substances
Injections
Anaesthesia

Lay terminology
Genetic Analysis and Testing
Appendix 1:
-Witness form
Appendix 2:
-Revocation of consent form
Appendix 3:
-Sample partner release form
Websites for further assistance
-National Statement Section 4
Download the templates today from NationalPICF.com.au
Here you can download the supporters permission form
Feedback

Thank you for taking the time to provide this feedback.

Email
you@domain.com.au

Overall, what were your first impressions?

- Poor
- Satisfactory
- Very Good
- Outstanding

Anyone can submit ideas or suggestions on the templates.

All feedback is compiled and reviewed at our regular template steering committee meetings. The next meeting date is on the main page of this website.

Find Out More
Project Team
Sponsor: Bellberry Limited
Chair: Kylie Sproston
Project Manager: Simon Windsor

Steering Committee

1. PICF Template Part A
   Standard Information
2. PICF Template Part B+C
   Study Specific
   Information and Consent
3. Supporting Resources
   and IT platforms
4. Consultation and
   Education
International Perspective in 2016

CTTI interviewed 25 experienced observers to identify limitations

- Reform excessively long Informed consent
  - Participants may not read, not be able to comprehend and simply sign the document

- Potential improvements:
  - Modified formatting and graphics
  - Appropriate grade and health literacy
  - Explaining technical terms in clear language

- Concerns around detail required on:
  - Procedures, Risks and Benefits
International Perspective in 2016

- eConsent Initiative (June 2015)
  - Aim: Create a common approach for the electronic consenting of patients using an array of digital elements and process efficiencies
  - Potential improvements:
    - Easy-to-understand clinical trial information
    - Establish a consistent and aligned process for Ethics Committees
    - Improve review/approval process
International Examples

The separation of "general research" and "study-specific" information is already being successfully used in Europe.

- Dutch PICF Template – Part A : Booklet (PDF)
- Dutch PICF Template – Part B and Part C (WORD)

Medical Scientific research - General information on the subject

The brochure provides an introduction to medical research and participation. Then discusses participant rights and obligations as well as study monitoring. Includes photos and advice boxes.

Published: 09/2014 by CCMO
Length: 24 pages
International Examples

Educational booklet and brochure developed by Singapore National Medical Research Council (Clinicalresearch.org.sg)

Published: 2010
Length: 14 pages

Published: 2010
Length: 2 pages
Thank you

Download the forms today

For hard copies of Part A - send request to:
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Or Call 08 8361 3222

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