InFORMed

Redesigning Consent to Research

USER GUIDE

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About the InFORMed PICF Template

The InFORMed Participant Information and Consent Form (PICF) Template is the product of CT:IQ's InFORMed Project: Redesigning Consent to Research. The InFORMed project has developed a simplified, consumer-centred PICF template for use across Australian health and medical research. The template was developed by a project team, including representatives of industry, sites, researchers, Human Research Ethics Committee Chairs and members, and consumers. A beta-testing version of the InFORMed template and user guide were released for feedback between June and December 2023. The first version of the InFORMed Template and User Guide was released in June 2024.

This updated version (March 2026) incorporates changes made based on subsequent user feedback, including additional content on genomic research and withdrawal forms.

Consumers in Research

As defined in the Australian Clinical Trials Alliance (ACTA) and CT:IQ Consumer Engagement Toolkit, consumers in health care are patients, potential patients, carers and people who use health care services. Consumers can also be research participants or potential participants. For clarity in this User Guide, the term '**consumer**' is used to refer to the broad suite of persons researchers may actively involve in the planning of the project and developing their consent materials. The terms '**potential participant**' and '**participant**' are used to refer to specific individuals with whom researchers may be having consent discussions, or who are participating in a research project.

A Flexible Template for Most Health and Medical Research

The template has been designed to provide a suitable starting point for most kinds of health and medical research conducted in Australia. All parts of the template are guidelines and not rules: it can be changed as needed to suit your project and/or consumer group. You should consult with your institution on any legal obligations that may need to be addressed in your PICF.

We encourage you to think critically about your project and potential participants when developing your PICF. While the template provides a framework, consumer involvement is essential to make sure the PICF meets the needs of the target population. This is particularly important when working with groups who may have specific communication needs, such as Aboriginal and Torres Strait Islander people, people from different cultural, linguistic or ethnic backgrounds, people with different communication abilities, low literacy, low health literacy, and children.

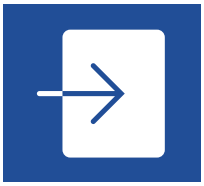
Find out more about the InFORMed Project

To see more information about the InFORMed project, please visit www.informedpicf.com.au.

About the InFORMed User Guide

The InFORMed User Guide has been developed to provide guidance when using the template.

This user guide has four parts.



Part 1 - Getting started with the template

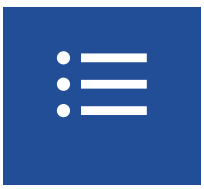
Find some initial tips and tricks for using the template.

Part 2 – Key principles for consumer-friendly consent forms

Follow these principles to make sure your PICF is simple, easy to read and consumer-focused.

Part 3 – Layered consent and supplementary information

Find information about what layered consent is and how to provide supplementary information.



Part 4 – Breaking down the template

Go through each section of the template in more detail.

Part 1: Getting started with the InFORMed PICF template

Choose how you will refer to your research project.

Consistency is important throughout your PICF. We have used the term 'project' and 'research project' throughout our template, but you can choose to use 'study', 'research study' or another relevant term. Make sure you are consistent through your documents.

Consider how you will address participants

For most research projects, you should address the potential participant as 'you' throughout the PICF. This extends to research where the participant is unable to provide consent, such as research with young children.

For the purposes of the template, the form of address is given as "the participant" but we strongly encourage you find a form of address that meets the needs of your project such as "your child" or "your partner" as an alternative to "the participant".

Think critically about what level of information is needed for your PICF.

The template provides you with a starting point for developing a concise, easy-to-understand PICF. It gives you guidance but should also be adapted to meet your needs.

You should think critically about the information you provide in the context of your project and intended audience.

For example, the level of detail you provide in a PICF for a brief, online questionnaire will be different from the detail you provide for a complex clinical trial. Think also about what can be assumed to be common knowledge.

Follow the instructions in the template.

We have used 3 text formats to help you use the template:

- Plain black text – this text is the content of the template that is likely to be relevant for most research projects. You can choose to keep the black text exactly as written. Otherwise, you can adapt the content to best meet the needs of your research particpants. If this text is not relevant to your research project, it can be deleted.
- **<Orange text>** - needs your attention. It may be relevant to your research project but will often need to be changed depending on your participant needs. You may need to choose one option of several scenarios presented, or you may need to fill in project specific information.
- **[Blue text]** - this text provides instructions throughout the template. Please delete the text after you have read it. It is not to be included in the final PICF.

Tip: you may find it useful to search for <> and [] at the end of drafting to make sure you have removed all the prompts and instructions.

Part 2: Key principles for drafting PICFs

Principle 1 – Know your likely participants and be inclusive

Understanding who your audience is, including potential participants, will help you tailor your content and make your PICF relatable.

Principle 2 – Write the same way you talk

Using everyday words and writing in a conversational tone helps you engage with your audience.

Principle 3- Use the active voice and be direct

Using active voice and personal pronouns like 'you' and 'we' makes it clear who is doing what.

Principle 4 – Keep your message relevant, short and simple

Having a clear message will help potential participants understand what you are asking them to do.

Principle 5 – Be consistent

Consistency helps potential participants understand what you are saying, especially when introducing new concepts.

Principle 6 – Make the layout easy to navigate

An uncluttered document with a clear hierarchy of information helps potential participants quickly find and absorb relevant information.

Principle 7 – Use visual aids that add meaning

When used in the right way, visual aids such as images and tables can add meaning and reduce overwhelm from large amounts of text.

Principle 8 – Involve consumers

Consumers can help you co-write your PICF or tell you if your PICF is easy to read and understand and whether it contains the right information.

Principle 1: Know your likely participants and be inclusive

Why is this important?

Knowing who your audience is will help you decide what words to use and what information to provide. Understanding diversity and using inclusive language will make sure your PICF is respectful to all.

How can I do this?

Learn about your audience

Think about who will be reading your PICF, including potential participants. You can think about things they may have in common like their age, background, level of education, and life experiences. If you do not know much about your target audience, you can conduct a literature search, consult an organisation that works directly with the group you are targeting, or conduct a survey or focus group with a small group of people from your target group.

Consider the diversity of the population

When considering who your audience is, also think about the diversity within your audience and the ways in which this might impact the accessibility of your language and consent processes. Consider their diverse needs, wants and values, language, ethnic and cultural backgrounds and beliefs, as well as diversity in their communication abilities such as hearing, literacy, numeracy and health literacy levels.

Use inclusive language throughout your document

Inclusive language is communicating in a way that is respectful to all people, acknowledging that we all have varied identities and experiences. This means avoiding biases, slang and expressions that exclude groups of people. Inclusive language is respectful of the diversity we have in our communities and avoids expressions that are sexist, racist, or biased to any particular group of people.

Where can I read more about this?

The Australian Government Style Manual

- The Australian Government (August 2022) Style Manual: User research and content.
- The Australian Government (August 2022) Style Manual: Accessible and inclusive content.
- Reading Writing Hotline (2020) Reader friendly communication: A guide to using plain language.
- Centers for Disease Control and Prevention (2022) Health Literacy Guidelines & Tools.

Principle 2: Write the same way you talk

Why is this important?

Using a conversational tone and language people are familiar with means they can quickly understand what you are saying.

How can I do this?

Use everyday words

Try to use common words that people understand and use themselves. Avoid technical jargon where possible. If you need to use technical jargon or medical terms, always provide a definition.

Example 1.

Instead of '**participate**', say '**take part**'.
Instead of '**hypotension**', say '**low blood pressure**'.

Example 2.

"You will have an electrocardiogram (ECG). An ECG is a measurement of the electrical activity of your heart to test how the heart is working."

Use a conversational tone

Write in the same tone that you would use if you were talking with a potential participant. This will help your audience engage with what you are saying and build understanding and trust.

Aim for a grade 8 reading level

Readability tools are available online that can help you assess the reading level of your PICF. An example is the Sydney Health Literacy Lab Health Literacy Editor. These check the sentence length, word choice and use of passive language. The standard guideline is to aim for a grade 8 reading level, but this needs to be adjusted based on your audience.

Where can I read more about this?

- The Australian Government (August 2022) Style Manual: Plain Language and Word Choice.
- The Australian Government (August 2022) Style Manual: Voice and Tone.
- University of Michigan (2020) Plain Language Medical Dictionary.

Principle 3: Use the active voice and be direct

Why is this important?

Using active voice, rather than passive voice, helps your audience understand who is doing what. Using personal pronouns like 'we' and 'you' is clear and direct and gives your writing a familiar and friendly tone. This will improve the readability of your PICF.

How can I do this?

Use 'we' and 'you' wherever possible to make the PICF more personal

To use active voice, make sure your sentences always have a subject performing the action. This is different to passive voice where the subject is undergoing the action. The application of this principle is best demonstrated through examples:

Example 1.

Instead of: **You are invited** to take part in a project

Say: **We invite you** to take part in a research project.

Example 2.

Instead of: The results **will be sent** to the **participant**.

Say: **We will send you** the results.

Example 2.

Instead of: The medicine **must be taken** before meals.

Say: **Take** the medicine before meals.

Tip

Some people may find this level of directness uncomfortable. When discussing the PICF with participants, you should check in with them how the information is being received.

Where can I read more about this?

- Centers for Disease Control and Prevention (2019) The CDC Clear Communication Index.
- The Australian Government (August 2022) Style Manual: Sentences.

Principle 4: Keep your message relevant, short & simple

Why is this important?

Clear messages help potential participants understand what you're trying to communicate and the action you want them to take. By keeping your message relevant, short, and simple, you'll be more likely to engage your audience and get the outcome you want.

How can I do this?

Focus on what potential participants need to know, not on what you want to tell them

Your PICF should help potential participants understand what your project involves. When you are writing the PICF, try to put yourself in a potential participant's shoes. Ask yourself, 'What would I need to know to make an informed decision about taking part in this project?' And importantly, 'What wouldn't I need to know to make an informed decision about whether to take part?'.

Make it clear what you are asking the potential participant to do

Be direct in communicating your message and don't provide 'nice to know' information just for the sake of it.

Keep sentences and paragraphs short

Keep sentences to 20 words or fewer and use only 2 to 3 sentences in each paragraph. Each sentence should contain only one idea. Each paragraph should cover one theme or topic. Remove unnecessary words like 'very' or 'actually' and reduce the amount of punctuation used.

Where can I read more about this?

- Canberra Health Literacy (2023) Writing Health Information for Consumers.
- US Agency for Healthcare Research and Quality (2015) Tips on Writing a Report on Health Care Quality for Consumers.
- Sydney Health Literacy Lab Health Literacy Editor.

Principle 5: Be consistent

Why is this important?

Using consistent language and formatting will help your audience understand what you are saying, especially when you are introducing new concepts. Using the same terms and phrases throughout the PICF will help potential participants follow along more easily.

How can I do this?

Use the same words throughout your writing

Avoid using different words or phrases to refer to the same thing, as this can be confusing. Using the same language to refer to a concept means your audience only needs to learn what that word or phrase means once. This helps the potential participant focus on the message you are communicating rather than learning new terms.

Keep formatting consistent and uniform throughout the PICF

Using consistent formatting, such as font style and size, makes it easier for potential participants to scan the content and understand the main points. Remember to use Australian spelling.

Where can I read more about this?

- The Australian Government (August 2022) Style Manual: Spelling.
- The Australian Government (August 2022) Style Manual: Editing and Proofreading.

Principle 6: Make the layout easy to navigate

Why is this important?

Clear and uncluttered pages are easier to read. Large sections of text can be overwhelming and make it difficult for your audience to find the information they need. By making the layout easy to navigate, the reader will be able to quickly find and absorb the most important information. This will help the potential participant stay focused and engaged with your content.

How can I do this?

Use subheadings to separate topics within sections

Subheadings can be a guide or an outline to the content of each section. Clear subheadings let the reader scan down and look for the information they want. Try to make subheadings specific rather than generic. For example, instead of 'Symptoms' say 'Symptoms of heart disease'.

Use bulleted or numbered lists

Using lists can break up large amounts of information and make it easier to follow. Be careful not to use lists that are too long. If you have a long list of items, use subheadings to break up the list.

Use at least size 12 font

Using 12 to 14 size font is ideal. Anything less than size 12 will be too small for many people to read. Consider using dyslexia-friendly font.

Use bold text to emphasise words or phrases

Avoid italics or underlining as they are hard to read.

Break up large chunks of text with white space

Use white space to break up large blocks of text and make it easier for the reader to scan the document.

Where can I read more about this?

- The Australian Government (August 2022) Style Manual: Structuring Content
- Reading Writing Hotline (2022) Reader friendly communication.
- Teacher Professional Development (2025) 15 Best Dyslexia-Friendly Fonts for Students That Boost Reading Confidence.

Principle 7: Use visual aids that add meaning

Why is this important?

Visual aids, like images, diagrams, tables, and charts, can add meaning to your text and make it more engaging. Visual aids can help the consumer to understand complex ideas.

How can I do this?

Consider alternative ways to communicate information

Tables and charts can be effective ways to present a large amount of information; however, be mindful that not everyone is able to interpret these easily.

Choose effective, relevant, and appealing images to help communicate your message

Use images, such as diagrams, that help explain text. Different people interpret pictures in different ways so make sure you use images that are relevant to your audience. Avoid using images that are abstract or for aesthetics only. Make sure the images you use are high quality.

Always label visual aids with captions

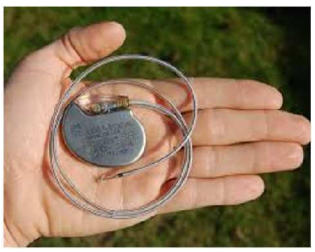
Place the visual aid near the text it is linked to and use captions to label each visual aid.

Example 1.

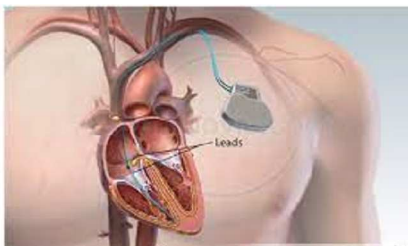
What is a pacemaker?

A pacemaker system consists of a pacemaker and a lead that anchors into your heart. A pacemaker is a minicomputer that sits in your chest and is connected to your heart by a lead. This lead is anchored into your heart muscle, so it does not move. The lead picks up your heartbeat and sends these messages back to your mini-computer, which makes sure your heartbeat stays regular.

Picture 1: What a pacemaker looks like



Picture 2: How a pacemaker sits in your chest



Reference 1

Where can I read more about this?

- Centers for Disease Control and Prevention (2022) Health Literacy Guidance & Tools.

Principle 8: Involve consumers

Why is this important?

Involving consumers in the development and review of your PICF can help to make sure the information you provide is relevant and easy to understand.

How can I do this?

Check what systems your organisation already has for involving consumers

Many organisations have systems in place for involving consumers in health and medical research. Ask around your workplace to see how you can use existing committees or relationships to connect and work with consumers.

Choose an approach to involving consumers that is feasible for your project

There is no single approach to involving consumers in the development of your PICF. You should consider when and how you will work with consumers and allow for this in your budget. Plan how you will do this at the start of your project, ideally before you have started developing your PICF.

Access the many resources that are available to help you involve consumers

There is no single approach to involving consumers in the development of your PICF. You should consider when and how you will work with consumers and allow for this in your budget. Plan how you will do this at the start of your project, ideally before you have started developing your PICF.

Where can I read more about this?

- ACTA and CT:IQ (2019) Consumer Involvement and Engagement Toolkit.
- Western Australian Health Translation Network (2018) Involving Consumers in Health and Medical Research.
- Tanya Symons, CT:IQ InFORMed Project (2023) : A report on consumer values and preferences regarding participant information sheets and consent forms.
- NSW Regional Health Partners (2025) Doing Research Together.

Part 3: Layered consent and supplementary information

What is layered consent?

The template uses the concept of layered consent to assist in producing a shorter, simpler and easier to understand PICF. Layered consent consists of two types of information:

- Key information: the information that a reasonable potential participant would consider important to make their decision on whether to participate in a research project
- Supplementary information: additional information that may be considered useful by some potential participants, but for others may obscure the information essential for deciding whether to participate in a research project.

Layered consent has two characteristics:

- A physical separation of the key information and supplementary information.
- Potential participants have enough information to consent to participate in a research project without reading/accessing supplementary information

A layered consent approach allows your audience to access the information they need at the time they need it.

How do I use the template to provide layered consent?

The template will help you provide the key information for your research project. If needed, supplementary information should be provided in ways that are suitable for you and your potential participants, such as a project website or an appendix.

How do I decide what information is 'key information'?

The best way to find out what you need to include as key information in your PICF is to speak with your consumers. Find out what information they consider to be important to make a decision to participate in your project.
See each section in part 4 of this user guide for more information about what may be included as key information under each heading in the template.

Where can I read more about this?

- Please refer to Tanya Symons, CT:IQ InFORMed Project: A report on consumer values and preferences regarding participant information sheets and consent forms (2023) for further information about layered consent.

What do I provide as supplementary information?

Not all research projects will need supplementary information. If all relevant information is covered by the key information, the PICF you create from the template can be sufficient. For other research projects, supplementary information might include:

- Information that is important during participation, but is less relevant at the time of consent, such as detailed assessment schedules and practical information like travelling options and how to get there
- More detailed information about the project and intervention under study including non-material risks (those that do not meet the threshold for inclusion in the PICF), data retention and sharing, or the project's Data Management Plan
- Links to external resources such as ANZCTR or clinicaltrials.gov

The type of information required will differ between research projects, and consumers are best placed to tell you what information they want and need in a PICF.

What is the best way to provide the supplementary information?

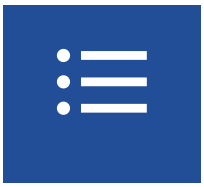
There are many things to consider when deciding how you can provide supplementary information for your research project.

Ask yourself:

- Who is my target audience?
- How many people may need access to this information?
- How much information do I need to provide?
- When will this information need to be available?
- What resources do I have available to me?
- Will I need to update this information regularly?

You might consider:

- Putting all the information together into a booklet to give to potential participants
- Creating a website for your research project where you can have all the information easily accessible
- Putting together a list of links to external resources you can email to potential participants.



Part 4: Breaking down the template

In this part of the User Guide we go through each section of the template and describe what the purpose of the section is, concepts that should be included, and examples or tips for how to do this well.

This section also includes guidance for using withdrawal forms.

Header, Title and Footer

Purpose:

To give your audience the administrative details of the research project.

Include:

- Your organisation's logo in the header
- The short name of your project
- The full name of the project
- The name of the Principal Investigator
- The name of the organisation acting as the Australian sponsor
- Site name (if needed for your project, for example, if you are doing a multi-site project)
- The protocol number and date in the footer

Tips

Think about the readability of your project's name.
Often, research projects have complex names that are hard to read and understand. Mixtures of upper and lower case can make words hard to read. Consider including a simplified project name in your study protocol and including this in your PICF. This simple name should use plain language.

Remember to update your footer.
Use the footer for version control. Make sure to update the version number and date here when creating a new version of your PICF.

What am I being invited to do?

Purpose:

To invite the potential participant to take part in your research project and tell them why they are being invited to take part.

Include:

- A definition of who 'we' is as used throughout the PICF, for example 'the research team at ABC hospital'. The definition will depend on the context of your research project.
- A statement inviting the person to take part in the research project.
- A short sentence that describes the key research topic/question of your research project.
- The reason that the person has been asked to take part in the project.
- A brief summary of what they will need to do in the project, such as 'fill out yearly surveys about your health for the next ten years'.
- The total number of people who will take part in the project and from where they will be recruited. If it is relevant, you can add the number of sites in the project.
- A statement asking the person to read the PICF and make sure that they understand what it says. List who they may like to talk to about the project.

Tips

Keep this section short.
Provide only one or two sentences about your research project, leaving more details to the next section.

Avoid bias in the way you present information.
Explain what is being investigated to test the study hypothesis rather than suggesting that the hypothesis will be established.

Examples

Example 1

Biased:
The University of Queensland invites you to be part of a **groundbreaking** study of metformin for kidney disease. You have been invited to take part because **your doctor thinks that your kidney disease could benefit** from taking this drug.

Unbiased:
We, the study team at the University of Queensland, invite you to be part of a study that looks at a drug called metformin – 'the study drug'. You have been invited to take part **because you have kidney disease**. We want to find out **if** the study drug can be used to treat kidney disease.

What is the purpose of this project?

Purpose:

To give the potential participant the key information that they need to know about the background, context and aim of your research project.

Include:

- A short description of what the project is about
- A short description of how you plan to share the information you discover in the project

Tips

Limit this section to key information.
Further detail can be provided in the supplementary information if you decide that is needed for your research project.

Focus on the purpose, not what the project entails.
Do not provide detail about what the potential participant will need to do if they take part. This will come later in the PICF. More detailed information could be provided as supplementary information in the "Where can I find more information?" section.

Examples

Example 1
In this project, we will explore how getting back to 'normal life' in 2022 has shifted body image for men taking part in this survey. We want to find out about your experiences with food, exercise, body image and appearance satisfaction and if they were impacted by lockdowns in Australia. We hope that the results from this project will inform policy and educational content for men in Australia and around the world.

Reference 3

Example 2
In this project, we will gather safety data to seek approval to use this pacemaker system in Australia. This new pacemaker is an updated version of pacemakers that are currently approved for use in Australia. To get a new pacemaker system approved for use in Australia, it must first be used and examined in a research study like this one.

Reference 1

Do I have to take part and can I change my mind?

Purpose:

To tell the potential participant that their participation is voluntary and that they can withdraw at any time.

Include:

- A statement that tells the potential participant they can say yes or no to participating.
- If relevant to your project, a statement that describes the alternatives to. taking part, including standard of care options.
- A statement describing how the participant can withdraw if they want to.
- Any implications of withdrawing such as whether their data and samples will be retained, whether any additional data will be collected or analysed.
- A statement explaining that the study, or a participant's participation in the study, might need to be stopped for various reasons.

Tips

Think about the information that may be relevant to the potential participant.
For example, you can tell them that not taking part won't affect their relationship with their doctor, if that might be a concern for them.

Remember to use everyday words.
Use the term 'stop taking part' instead of withdraw in the PICF because this is a more familiar term for most people.

Think about the implications of withdrawing.
You might consider things like:

- Information that might already have been shared about the participant
- Any irreversible effects of participation such as surgery, xenotransplantation or an implanted medical device
- Any activities that you will ask participants to take part in after they have stopped taking part, such as safety activities or return of an investigational product.

What do I have to do if I take part?

Purpose:

To provide details about what the potential participant will need to do if they take part.

Include:

- The total duration of participation in the research project.
- Any changes to their lifestyle or medications they will need to make, such as abstaining from alcohol for the project duration or toxicity issues from medications or vaccines that may impact a fetus for a period of time.
- The types of activities participants will do, where these will take place and how long they will take, including any options for how participants undertake activities (eg if an activity can be done either in-person or online). If there are complicated screening activities, these should be included here.
- Any specific instructions that may be important to the potential participant, such as if they will need to fast for a blood test.
- Details about what will happen at the end of their project participation, such as access to study drug.
- Details of information they will receive at the end of the project. You should aim to provide at minimum a plain language summary, but do not promise to provide information that you may not be able to carry through with.
- A description of any optional parts of the project to which the potential participant will be asked to provide consent.
- Details of inconvenience or expenses that could be incurred if the potential participant takes part in the project.

Include information about any reimbursements or payments the participant may receive.

If participants are to be reimbursed, the processes they would need to follow should be described either in the PICF or in supplementary information. This could include submitting claim forms, keeping receipts, etc.

If the participants are to be paid for their time or inconvenience, this should include the method and timing for payment, for example "you will receive a $100 gift card after your first visit, and a $150 gift card after your final visit".

It should also include a timeline for how long processing reimbursement or payment may take.

Tips

Use visual aids to help make it clear.
Use a timeline or other image to display information if this may help make the information easier to understand.

Consider how consumers may use the PICF.
Some participants want to have a project timeline that they can tear out for future reference. If this may be useful to participants in your research project, consider having this section on its own page.

Stick to key information.
Keep this section to the key information the potential participant will need to decide whether to participate. Detailed schedules should be provided in supplementary information if needed.

Provide descriptions of specific assessments if needed.
If your research project has medical tests or assessments, like MRIs or specific questionnaires, consider providing a table that gives a short description of what these are.

Examples

Example 1

If you want to take part in this project, you will complete a short online survey. This will take about 10 minutes.

Reference 3

Example 2

What part of the project?	What do I have to do?
When you start the project	If the project is suitable for you, we will ask you to complete a short questionnaire about your quality of life.
Implantation	If you decide to join the project, we will ask you to: • take an ECG • implant a new pacemaker.
Hospital discharge	As part of your hospital discharge, we will: • check your pacemaker is working properly • take a chest x-ray • take a second 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. You should always carry this card with you.
Months 1, 6 and 12	You will be required to attend the hospital pacemaker clinic three times. During these visits we will: • check your pacemaker is working properly • take an ECG • take an echocardiogram at month 12 if your doctor thinks you need it • ask you to complete a short questionnaire about your quality of life at month 12.
After the study ends	Your doctor and the pacemaker clinic will continue to see you and monitor you as per standard of care. The pacemaker will remain in place to manage your heart condition.
After the project completes	We will send you a plain language summary of the results of the project.

Reference 1

What are the benefits of taking part?

Purpose:

To provide a balanced description of the benefits from taking part in your research project.

Include:

- A description of any benefits such as helping others
- A statement describing whether there are any direct benefits to the participant.

Tips

Consumers told us that the altruistic reasons for taking part in a research project were important and should not be downplayed.

In an interventional clinical trial, there are benefits to consumers that should also be included if relevant. These include things like:

- More regular monitoring.
- More thorough monitoring.
- More (or another) specialists/health professionals reviewing your treatment.
- Receiving optimal care/best available standard of care according to latest research/current evidence base.

Examples

Example 1
Your child will receive the best individual clinical care available and ongoing education on lung health. This study will also increase our understanding in managing lung problems, so we can work with health staff to find better clinical pathways and strategies to prevent ongoing lung problems and disease in young Indigenous children.

Reference 5

What are the risks and discomforts of taking part?

Purpose:

To give the consumer the key information about any risks and discomforts they may face if they take part in the research project.

Include:

To give the consumer the key information that they need to know about the background, context and aim of your research project.

- A clear explanation of any different or additional risks or discomforts that may come from participating in the research project vs other courses of action (e.g., standard of care treatment).
- Description of key risks under suitable subheadings. Consider using one or more of the following subheadings as relevant to your project, or add your own:
    - Risks of medications/devices used in the project
    - Risks for unborn and newborn babies
    - Risks if you are taking other medicines
    - Risks from exposure to radiation
    - Risks from genetic analysis
    - Chance of distress
    - Breach of confidentiality
    - Other key risks not covered in the template.

Tips

Focus on risks that are common or severe.
This section should focus on key risks. Key risks are those risks that a reasonable person in the position of a potential participant would need to make an informed decision whether to take part in the project. It can also include risks that you know, or should reasonably know, a potential participant wants to be given before deciding whether to take part.

Speaking with consumers when developing your PICF can help to identify what risks are key for your audience. The participant is most likely to be concerned about risks that are common, even if they are mild. They are also likely to be concerned about severe risks, even if they are rare. Avoid listing risks that relate to clinical care and not project participation.

Use the supplementary information effectively.
If your project uses medicines that have long lists of potential side effects, consider providing information about the non-key risks through supplementary information. If you feel you need to explain how a treatment or test (e.g. genomic testing) works for people to appreciate the risks, consider supplying this as supplementary information for potential participants to read before the PICF.

A balanced presentation is important to decision-making.
Make sure you are balanced in the presentation of risks in a way that supports the potential participant in decision making. Providing excessive details of risk can lead to the nocebo effect. This means a participant expects and experiences side effects because they believe the medicine they are taking will cause harm. See Tanya Symons, , *CT:IQ InFORMed Project: A report on consumer values and preferences regarding participant information sheets and consent forms* (2023) for more information about the nocebo effect.

Communicate risks in a way that is meaningful to the consumer.
You need to provide potential participants with a clear explanation of how the risks of taking part are different from the risks of not taking part. For example, saying 'these risks are the same as standard of care' or 'you will get two extra MRIs' clearly shows the risk level.

Examples

Example 1 (drawn from the Emory Clinical Cardiovascular Research Institute Example 6 Short Consent.pdf)
There are no additional risks to you from taking part in this project. There are bleeding risks associated with both drugs. The risks of [control drug] are not any different whether you are in the study or not. Additional risks associated with [study drug] include, stomach discomfort, back pain, chest pain and shortness of breath. You can ask us for more information.

Example 2
There are potential risks to you from taking part in this project. The questions in the survey may cover sensitive topics and this may cause you distress. If this happens, you can take a break from or stop the survey at any time.

You can contact Lifeline at any time on 13 11 14. If you want, we can provide someone who is not part of the project team to give you support.

Reference 3

Example 3
There are known side effects of taking atorvastatin (Lipitor®). However, there may also be side effects that the researchers do not know about. The side effects that we know about are in the table below.

Very common side effects More than one in 10 people will experience these side effects	**Common side effects** More than one in 100 people will experience these side effects	**Rare side effects** People are unlikely to experience these side effects
• Headache • Muscle pain • Constipation • Feeling sick • Increased blood sugar levels	• Skin rash • Itching • Hives	• Allergic reactions • Liver injury • Severe muscle disorders

Reference 4

How will my information and samples be used for this project?

Purpose:

To tell the potential participant how their information and samples will be collected, stored, and managed as part of the project. This is different from the next section, which tells the potential participant how their information and samples may be shared for other research projects in the future.

Include:

- How you will collect information and/or samples, including whether you will collect it from third parties.
- Any third-party services that may access/analyse participants' information or samples, including any data linkage activities.
- How, where and for how long you will keep information and/or samples.
- Whether and how you will share information discovered during the research with the participant or their relatives.
- Whether you will share information with others as part of this project. This may include with other healthcare professionals, analytical service providers, or if legally obligated.
- The right of participants to be told what information has been collected about them, and to correct that information if it is not correct.
- That consent to participate includes consent for certain project information to be made available for publication and, if relevant, data repositories. This should include the limitations on what information will be shared in this way to maintain privacy protections (e.g., aggregated data, minimal data).
- Details of the relevant Privacy Officer participants can contact if they have complaints about how their personal information has been managed. This may be the same or different to contacts listed in the complaints section under "who has reviewed and approved this project?"

Tips

Keep it short and simple
If you focus too much on privacy information, it can distract the reader from other risks, like those associated with study drugs or procedures (Anderson et al, 2017). All potential participants should receive general information about how you will protect their privacy and confidentiality. More details should be given through supplementary information. This may include a copy of a privacy policy or data management plan.

Publication of information
You should let participants know what information will be published or otherwise made available, for example to upload to a data repository. Consider what steps you are taking to minimise the identifiability of information being shared, e.g., through providing minimal data, aggregating, and/or fully anonymising information (some information on how to do this is available from the European Union Art 29 Data Protection Working Party), and restricting access to secure remote environments.

Consider adding links to available resources.
Here are some that explain how information is anonymised and how data linkage works:

- Data Linkage: Benefiting planning, research and evaluation of Health, Education and Community Services
- Introduction to Data Linkage Series - Part 1 Introduction to data linkage

How will my information and samples be used for this project?

Tips

Where can I read more about this?

Emily Anderson, Susan B Newman & Alicia K Matthews (2017) 'Improving Informed Consent: Stakeholder Views' 8(3) AJOB Empirical Bioethics.

Information and Privacy Commission (NSW) (June 2019) Fact Sheet: Consent and Bundled Consent.

Australian Government Office of the Australian Information Commissioner Consent to the handling of personal information.

Examples

Example 1:

Blood samples will be sent to the hospital laboratory for normal tests. Any nasal or sputum specimens will be sent to our research laboratories to test for usual bacteria and viruses. We will ask you if we can keep these swabs, without your child's name on them, for future research (with ethics approval). It's your choice; you can choose to have the specimens destroyed at the end of the study.

Reference 5

Example 2:
[Your and/or your child's] data obtained through this research study:

- will be accessed by those involved in **[your/your child's]** care and personnel working on this research study;
- may be released to genetic services to help with the care of other family members, without **[your and/or your child's]** identity being revealed to family members wherever possible;
- will be stored and made available to other research studies if you consent to donate **[your and/or your child's]** data for this purpose (optional); and
- will otherwise remain confidential, except as required or allowed by law.

Personal information (including **[your and/or your child's]** name, date of birth and address) will be removed and replaced with a unique study code. Only the minimum, necessary data will be shared with study researchers. This maintains **[your and/or your child's]** privacy, while allowing our study team to link any research findings back to **[you/your child]** if necessary. This will be important if there are findings that have implications for **[your/your child's]** future health care, so that it may be possible to contact you to return these results.

Reference 6

How will my information and samples be shared for future research?

Purpose:

To provide the potential participant with information about how their information and samples may be used in future research. Secondary use of data and samples can be valuable to future research and asking for this upfront removes the need for extra HREC approvals after this project is finished.

Include:

- The option for the potential participant to consent to sharing their information and samples for future research. This may be for any future research ('unspecified consent'), or for a narrower subset of future research, for example, into specific disease areas ('extended consent').
- Whether information about future research for which information or samples might be shared will be made available, e.g., through a website or study newsletter.
- Any limitations on withdrawing consent to future sharing of information or samples.
- How the potential participant can obtain further information, such as a Data and Sample Sharing Policy
- Whether the potential participant may be contacted about, or receive results from, future research projects, such as if there are incidental findings.

Tips

Offer potential participants choices if possible

Develop a Data and Sample Sharing Policy to share with potential participants on request. This should explain with whom data and samples will be shared and on what conditions. Conditions for sharing may include, for example, review by a Human Research Ethics Committee and/or Data Access Committee, and a commitment by recipients not to seek to reidentify participants. Additional information relevant to developing a Data Sharing Policy is available from ARDC's Data Sharing Policy Development Guidelines. An example of data sharing information that might be useful for potential participants is available from the George Institute for Global Health.

Consult with your consumers

Where possible, consult consumers on the scope of future data and sample sharing and any limitations that should be placed on sharing when developing the PICF. Particular care should be taken when it comes to sharing data generated by research involving Aboriginal and Torres Strait Islander peoples.

Where can I read more about this?

- Australian Research Data Commons (2023) Data Sharing Policy Development Guidelines.
- Lowitja Institute (2024) Taking Control of Our Data: A Discussion Paper on Indigenous Data Governance for Aboriginal and Torres Strait Islander People and Communities
- Genomics Australia PICF templates
- Global Alliance for Genomics & Health Consent Clauses for Genomic Research
- CT:IQ/ARDC (2026) Clinical Research Data Sharing Frameworks Projects

Who is running and paying for this project?

Purpose:

To tell the potential participant who is responsible for the research project.

Include:

- The name of the site organisation where the participant would attend visits
- The name of the sponsor and institution(s) running the research project
- How the project is being funded
- Other parties involved in the project, if relevant.

Tips

Consider if there is financial benefit to any parties involved.
You may want to consider including a statement about the financial benefit a sponsor, CRO or other entity may receive from the research project, if relevant.

Example

Principal Investigator has helped to develop [intervention] and owns a part of the company that would develop [intervention] for clinical use. This means that [Principal Investigator] could benefit from the results of the project.

What happens if something goes wrong?

Purpose:

To provide the potential participant with information about compensation options in case of injury from taking part in the study.

Include:

- Instructions of what to do in an emergency, if relevant to your research project
- Details on what kind of compensation processes are in place and what action the participant can take

Tips

Provide access to the compensation guidelines.
Participants in clinical trials should be given access the Medicines Australia or Medical Technology Association of Australia 'Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial' (depending on whether the trial includes medicines or medical technology). This information can be provided through a URL or in supplementary information.

Write your own description of compensation.
If you use the non-commercially sponsored clinical trials template text, you need to insert a description of compensation options. Remember to keep this concise, use plain language and avoid jargon. Further details on compensation can be provided in supplementary information if needed.

Who has reviewed and approved this project?

Purpose:

To inform the potential participant that the research project has been ethically reviewed and approved.

Include:

- The name of the approving Human Research Ethics Committee
- If the PICF has been created with, or reviewed by a consumer reference group, list their name here
- Who the participant can contact if they have a complaint that is related to ethics
- Who the participant can contact if they have a complaint that is related to the conduct of the study. This should be a phone that is reliably staffed and may be a different number to the ethics contact.

Key contacts and where to find more information

Purpose:

To provide the participant with all the relevant contact information in one place.

Include:

- A contact for the research project team. There may be a site contact as well as a central study contact.
- If there is a community liaison position, they should also be listed in this section.
- How the potential participant can find all supplementary information.
- More than one way of making contact, e.g. both a telephone number and email address.

Tips

See Part 3 of this User Guide for more information about layered consent and supplementary information.

Signature Section

Purpose:

To provide a place where the participant can sign to consent to take part in the research project.

Include:

- Statements which you need the potential participant to acknowledge to take part
- Optional consents with appropriate tick boxes if needed for your research project
- Make sure that these are consistent with the options discussed in the form,
- Include any options around future use of data or samples
- Include any opt-in study activities
- A place for the participant to sign
- A place for the person conducting the informed consent discussion to sign, if relevant to your project
- A place for a witness or other parties to sign, if required. Note that if an interpreter is used, the witness should not be the interpreter

Tips

Remember that the signature section is to get consent, it is not a checklist.
You do not need to provide a long list of statements that the participant must acknowledge to take part. Only include statements which you need the potential participant to provide explicit consent for, or where options are available.

Include additional signature blocks if required.
A witness is needed if the person giving consent has required assistance to read the form. In signing the form, the witness confirms that all written information was explained accurately to and understood by the person giving consent, and consent was given freely by them. The witness should be independent of the study team and any translator.

An additional signature is needed if the participant does not have capacity to consent to the project on their own behalf. This is usually a parent or guardian. You should still include a place for the participant to indicate their willingness to take part in the project (assent).

An interpreter should sign the consent form for people who do not read English. An interpreter signature block should include the statement that 'I have translated the information to the participant'.

Withdrawal Form

Purpose:

To document any decisions a participant makes when withdrawing from a research project.

Include:

- Any participant decisions that you need to document
- Signatures from the participant (or guardian) who is withdrawing, the member of the research team who has assisted them with this decision (if applicable) and any interpreters or witnesses who were part of this process (see guidance above for PICF Signature Section).

Important:

- A participant can withdraw their consent to participate in a research project at any time and by any means. A withdrawal form is not a mandatory requirement for their withdrawal of consent.
- Withdrawal forms are not the place to provide information about any implications of withdrawing from the project. That information should be provided by the research team to the participant prior to them deciding to withdraw from the research.

Tips

People withdrawing from clinical research have made a decision to cease involvement, so this form should be as short as possible – preferably under a page.

You should consider other ways to record when and how a participant has stopped participating. For example, this could be in a medical or research record.

Consider other methods to record feedback from the participant on why they are withdrawing from the research.

Example References

Examples 1-4 in this User Guide were developed as a part of the consumer consultation process for the InFORMed project from the following projects. The wording was workshopped by the project investigators and the InFORMed project team. Examples were also developed from materials 5 and 6, which were workshopped through the refinement of the Template.

1. *BIO|MASTER.Pacemaker - Pivotal study of the Amvia pacemaker and Solia pacing lead.* Sponsor: BIOTRONIK SE & Co.KG.
2. *Implementation of Metformin therapy to Ease Decline of kidney function in Polycystic Kidney Disease (IMPEDE-PKD) Randomised Placebo-Controlled Trial.* Sponsor: University of Queensland
3. *Predictors and Experiences of Body Image Among Sexual Minority Men During Australian COVID-19 Lockdowns: A Mixed-Methods Investigation.* Sponsor: Orygen
4. *The DA VINCI Study; **D**o st**A**tins fa**V**ourably modify atherosc**I**erotIc plaque in patients with differe**N**t levels of polygenic Cardiovascular (CV) r**I**sk?* Sponsor: Monash University
5. *Improving the management of health through long term follow up studies.* Template produced by Menzies School of Health Research.
6. *Template PICF/PGICF for research studies offering diagnostic genomic testing.* Template produced by Australian Genomics.