The InFORMed User Guide
How to use the InFORMed Participant Information and Consent Form (PICF) Template

Beta-Testing Version 1, June 2023

Contents

About the InFORMed PICF Beta-Testing Template (June 2023)

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 is working towards a simplified, consumer-centred PICF template. We developed a beta-testing template ('template') with consumer and research sector stakeholder consultation and with reference to the National Health and Medical research Council National Statement on Ethical Conduct in Human Research (2007) and ICH GCP E6 (R2). We have also used evidence-based plain language writing and formatting principles.

Consumers in Research

Throughout the template and user guide, we refer to 'consumers'. 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.

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. All parts of the template are guidelines and not rules: it can be changed as needed to suit your project and/or consumer group.

We encourage you to think critically about your project and consumer when developing your PICF. While the template provides a framework, consumer involvement is essential to make sure the PICF meets the needs of the population. This is particularly important when working with groups who may have particular communication needs, such as Aboriginal and Torres Strait Islander people, culturally and linguistically diverse communities, and children.

If your research project involves genetic and genomic research, consider whether the InFORMed template is right for you. If your research involves diagnostic or predictive genetic information, we recommend you use the Australian Genomics consent forms.

Focus on content, not on process

In the template, we have focused on the content of PICF, not the process of seeking consent more broadly. We have included a checklist in this user guide to help you make sure you are following the key steps in the informed consent process.

Find out more about InFORMed

To see more information about the InFORMed project, please visit the CT:IQ website.

Sources

ACTA and CT:IQ (2019) Consumer Involvement and Engagement Toolkit.

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2016). E6(R2)

National Health and Medical Research Council (2007, updated 2018) National Statement on Ethical Conduct in Human Research

About the InFORMed User Guide

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

This user guide has 4 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 to your consumers

Part 4 – Breaking down the template

Go through each section of the template in more details.

Part 1: Getting started with the InFORMed PICF template

Choose the formatted or unformatted version.

We have provided 2 versions of the template for you to use.

The formatted version has navy blue headers with icons next to each header. The included tables also have colours.

The unformatted version has no colours or images. Choose this version if you want to format the document in your own way.

Choose how you will refer to your research project.

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

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, experimental clinical trial. Think also about the likely existing knowledge among your audience.

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 project. If this text if not relevant to your research project, it can be deleted.

Yellow highlighted text – this text needs your attention. It may be relevant to your research project but will often need to be changed depending on your needs.

Orange 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.

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Part 2: Key principles for consumer-friendly PICFs

Principle 1 – Know your consumer and be inclusive

Understanding who your consumer is 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 consumer

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 concise

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

Principle 5 – Be consistent

Consistency helps consumers 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 the consumer quickly find and absorb relevant information.

Principle 7 – Use visual aids that add meaning

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

Principle 8 – Involve consumers

Consumers can tell you if your consent form is easy to read and understand and contains the right information.

Principle 1: Know your consumer 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. You can think about things 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, think about their needs, wants and value, cultural backgrounds and beliefs, and 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 (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). Understand Your Audience.

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 and a conversational tone

Try to use common words that people understand and use themselves. Avoid technical jargon and medical terminology. If you need to use technical 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 an informal way that is like you are chatting to the consumer. This will help the consumer engage with what you are saying and build trust.

Aim for a grade 8 reading level

Readability tools are available online that can help you asses the reading level of your PICF. 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 who your audience is.

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 consumers 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 the 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 research 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 the results to you.

Example 3

Instead of: The medicine must be taken before meals.

Say: Take the medicine before meals.

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 short and simple

Why is this important?

Clear messages help consumers understand, remember and act on your message. Consumers will understand what you're trying to communicate and the action you want them to take. By keeping your message 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 the consumer needs to know, not on what you want to tell them

Your PICF should help the consumer understand what your project involves. When you're writing the PICF, try to put yourself in the consumer's shoes. Ask yourself, 'What do I need to know to make an informed decision about taking part in this project?' And importantly, 'What don't I need to know?' For example, in a clinical trial, you don't need to tell consumers about their regular clinical care. Only tell them about the additional things you are asking them to do in this project.

Make it clear what you are asking the consumer 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.

Principle 5: Be consistent

Why is this important?

Using consistent language and formatting will help consumers understand what you're saying, especially when you're introducing new concepts. Using the same terms and phrases throughout the PICF will help consumers 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 the consumer only has to learn what that word or phrase means once. This helps the consumer 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 consumers to scan the content and understand the main points. Remember to use Australian spelling consistently.

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 consumers to find the information they need. By making the layout easy to navigate, the consumer will be able to quickly find and absorb the most important information. This will help the consumer 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 consumer scan down and look for the information they want. Try to make subheading 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 idea. Anything less than size 12 will be too small for many people to read.

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 consumer 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.

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 alternate ways to communicate information

Tables and charts can be effective ways to present a large amount of information. 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.

Here are some places you can look for free pictures and icons:

https://unsplash.com/

https://pixabay.com/

https://thenounproject.com/

https://undraw.co/illustrations

Where can I read more about this?

Centers for Disease Control and Prevention (2022) Visual Communication Resources.

Principle 8: Involve consumers

Why is this important?

Involving consumers in the development and review of your PICF is a way of making 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 the development of written information. Ask around your workplace to see how you can use what is already in place to involve 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 engage consumers. Plan how you will do this at the start of your project, before you have started developing your PICF.

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

There are many resources available that outline how to involve consumers in research and in the development of written information.

Where can I read more about this?

ACTA and CT:IQ (2019) Consumer Involvement and Engagement Toolkit.

Tanya Symons, *CT:IQ InFORMed Project: A report on consumer values and preferences regarding participant information sheets and consent forms* (2023)

Part 3: Layered consent and supplementary information

What is layered consent?

The template uses the concept of layered consent to produce a shorter, simpler and easier to understand participant information and consent form. Layered consent consists of two types of information:

- Key information: the minimum information that a reasonable person would consider sufficient to make a decision to participate in a research project
- Supplementary information: additional information that may be considered useful by some, but for others may obscure the information essential for decision-making.

Layered consent has two characteristics:

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

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

Where can I find more information about layered consent?

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.

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 alternate ways that are suitable for your consumers, such as via a project website.

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 is relevant and important to them.

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.

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:

- Detailed study background
- Lay summary of the study
- Further information about the intervention being studied
- Further information about privacy (like links to the institution's privacy policy)

- Further information about data retention and sharing
- Information that is important during participation, but not at the time of consent, such as detailed assessment schedules
- Links to external resources such as ANZCTR, clinicaltrials.gov
- Practical information for participants, like where to park and how to get there

The best way to decide what information to provide is to ask consumers. The type of information required will differ between research projects and consumers are the ones who can tell us what they want and need.

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?
- 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 consumers digitally or in paper copy
- 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 consumers

Part 4: Breaking down the template

Header, Title and Footer

Purpose:

To give the consumer 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
- Site name (if needed for your project, for example, if you are doing a multi-site project)

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 using a simplified project name for your PICF.

Remember to update your footer.

Use the footer for version control. Make sure to update this when creating a new version of your PICF.

What am I being invited to do?

Purpose:

To invite the consumer to take part in your research project and tell them why they are being asked 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.
- The reason that the person has been asked to take part in the project.
- A short sentence that describes the key research topic/question of your research project.
- The total number of people who will take part in the project and from where they will be recruited.

Tips:

Keep this section short.

Provide only one or 2 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

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. Around 250 people will take part in this study. They will be from different hospitals in Australia.

Example 2

We, the team at the Centre for Youth Mental Health, invite you to be part of a project that looks at body image experiences for men who are not straight/heterosexual. We want to find out how your body image experience was impacted during COVID-19 lockdowns in Australia. We are looking for up to 600 men to complete a 10-minute online survey.

What is the purpose of this project?

Purpose:

To give the consumer 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.

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 consumer will need to do if they take part. This will come later in the PICF.

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 how 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.

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 upgraded 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.

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

Purpose:

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

Include:

- A statement that tells the consumer they don't have to take part if they don't want to.
- If relevant to your project, a statement that tells the consumer that if they don't take part, they will still get the best available care.
- If relevant to your project, a statement that describes the alternatives to taking part.
- A statement describing how the consumer can withdraw if they want to
- Any implications of withdrawing such as whether their data and samples will be retained.
- A statement explaining that the study, or a consumer's participation in the study, might be need. to be stopped for various reasons.

Tips:

Think about the information that may be relevant to the consumer.

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:

- Loss of control over identifying sensitive information
- The irreversible effects of treatment such as surgery, xenotransplantation or an implanted medical device

Think about other things the consumer might need to consider if they want to withdraw, such as:

- Whether ongoing treatment will still be needed
- Safety considerations
- Where they will receive care

What do I have to do if I take part?

Purpose:

To provide detail about what the consumer will need to do if they take part.

Include:

- The total duration of participation in the research project.
- The types of activities the consumer will do, where these will take place and how long they will take.
- Any specific instructions that may be important to the consumer, like if they will need to fast for a blood test.
- Details about what will happen at the end of the project, like if the drug or device will still be available to them.
- Details of inconvenience or expenses that could be incurred if the consumer takes part in the project and whether these will be reimbursed.
- A description of any optional parts of the project to which the consumer will be asked provide consent.
- Any necessary information about what will happen when the project ends, such as access to a study drug

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 consumers want to have a page 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 consumer 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 a lot of 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.

Example 2:

What part of the project?	What do I have to do?

Consenting to take part in this project	If you are happy to take part in this project, you will be asked to sign the consent form.
When you start the project	You will visit the hospital for one hour. You will need to fast for 8 hours prior to this visit. The cardiologist and project coordinator will: • Ask you about your current health and lifestyle • Give you a set of questionnaires to complete • Conduct a physical exam • Collect a blood sample • Collect a urine sample to check if you are pregnant (if this applies to you)
Calculating your risk of developing heart disease	Your genetic risk of developing heart disease is calculated by analysing your blood sample and generating a 'polygenic risk score' (PRS). A PRS is one way that people can learn about their risk of developing a disease. Your PRS score is based on the total number of changes in your genes related to heart disease. Studies have shown that the higher the PRS, the higher the risk of developing heart disease. Initially, you will not be informed of your PRS but will find it out later in the project.
Getting put in a study group	You will be put into one of the following 2 groups: 1. **Randomised group** – you will receive treatment as part of this study and we will follow-with you regularly to see how you are going. 2. **Observational Registry group** – you will not receive any treatment as part of this study but will be cared for by your cardiologist or other doctor. We will follow-up with you to see how you are going. The group you are put into is based on your CTCA results and what level of blockage is found in your blood vessels. • If low level blockage is found, you will be allocated to the observational registry group • If mid level blockage is found, you will be allocated to the randomised group • If high level blockage is found, you will be allocated to the observational registry group

Example 3:

What part of the project?	**What do I have to do?**
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.
Implantation	During implantation we will: • 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.

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 statement describing whether there are any direct benefits to the consumer.
- Description of any potential benefits such as helping others.

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

What are the risks and discomforts of taking part?

Purpose:

To provide a balanced description of the potential risks and discomforts from taking part in your research project.

Include:

- A clear explanation of what different or additional risks or discomforts may come from participating in the research project vs other courses of action (e.g., standard of care treatment)
- Description of material risks under suitable subheadings. Consider using one or more of the following subheadings as relevant to your project, or add your own:
  - Side effects from medications
  - Risks for unborn and newborn babies
  - Risks from exposure to radiation
  - Chance of distress
  - Risks if taking other medicines
  - Other material risks

Tips:

Focus on risks that are common or severe.

This section should focus on material risks. Material 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 research project. It can also include risks that you know, or should reasonably know, a potential participant wants to be given before making a decision whether to take part. A known risk should be disclosed if it is common, even if its effect is minimal or severe, even if it is rare. Avoid listing risks that relate to clinical care and not study participation.

Use the supplementary information effectively.

If your research project uses medicines that have long lists of potential side effects, focus on the common and severe ones only. A comprehensive list can be provided in supplementary information.

A balanced presentation is important to decision-making.

Make sure you are balanced in the presentation of risks in a way that supports the consumer 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. The description of risks should not be inflated to mitigate institutional risk.

Communicate risks in a way that is meaningful to the consumer.

We need to provide people 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 2 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 no additional risks to you from taking part in this project. Your doctor has advised you that you need to have a pacemaker inserted even if you do not take part in this research study. The pacemaker system insertion procedure and associated risks will be explained to you by your doctor. You may need to sign a separate consent form for that procedure.

Example 3

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.

If I take part, what will happen to my information and samples?

Purpose:

To tell the consumer how their information and samples will be collected, stored and managed.

Include:

- How you will collect information, including whether you will collect it from third parties.
- How, where and for how long you will keep information.
- How, where and for how long you will keep samples.
- Whether you will share information with others as part of this project. This may include with other are providers, if legally obligated, for future research, or for research repositories.
- Whether consumers can access their own information or samples during or after the project
- How the consumer can get more details if they want and avenues to raise privacy complaints.

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 consumers 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.

Provide information about any required future sharing of information.

Your project might include the future sharing of information and samples to other parties, like research repositories. Include any potential for future sharing here if it is a condition of taking part in the research project. This is called 'bundled consent'. The next section deals with sharing for which the consumer may opt-in or -out.

Depending on the proposed sharing activity, a 'bundled' consent may not be sufficient to authorise sharing information that falls within Australian privacy laws. If you are using a bundled consent for future sharing, consider 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) as well as restricting access to secure remote environments.

Consider adding links to available resources.

Here are some ones that explain how information is anonymised and how data linkage works here and here.

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 Information Commissioner (March 2018) De-identification and the Privacy Act.

How may my information and samples be shared in the future?

Purpose:

To provide the consumer with information to support their decision whether to share information and samples for future research.

Include:

- Details of the kinds of research for which information and samples may be shared if consent is provided. 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 the information and samples being shared are identifiable or potentially identifiable, and any steps being taken to prevent reidentification.
- 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.

Tips:

Offer consumers choices if possible.

Consider whether to offer consumers choices about the kinds of research for which their information and samples may be shared. This can be a valuable way of respecting consumers, including their privacy interests, but requires systems to be in place to manage the datasets.

Develop a Data Sharing Policy.

Develop a Data Sharing Policy to share with potential participants on request. This should explain with whom data 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 consumers 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 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 (2021) Indigenous Data Governance and Sovereignty.

Who is running and paying for this project?

Purpose:

To tell the consumer who is responsible for the research project.

Include:

- The name of the sponsor and institution 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.

Who has approved this project?

Purpose:

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

Include:

- The name of the approving Human Research Ethics Committee
- Who the consumer can contact if they have a complaint that is related to ethics

What happens if something goes wrong?

Purpose:

To provide the consumer 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 consumer can take

Tips:

Provide access to the compensation guidelines.

All participants in Phase 1 & 2 studies must be given access to a copy of the Medicines Australia compensation guidelines. For all other clinical trials, the Medicines Australia compensation guidelines should be made available on request.

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 how the consumer can be provided in supplementary information if needed.

Where can I find more information?

Purpose:

To provide contact details or instructions for where the consumer can find more information.

Include:

- A contact from the research project team
- How the consumer can find supplementary information

Tips:

Find out more about layered consent.

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

Signature Page

Purpose:

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

Include:

- Statements to which you need the consumer acknowledge to take part
- Optional consents with appropriate tick boxes if needed for your research project
- A place for the consumer to sign
- A place for the person conducting the informed consent discussion to sign, if relevant to your project
- A place for a witness to sign, if required

Tips:

Remember that the signature page is to get consent, it is not a checklist.

You do not need to provide a long list of statements that the consumer must acknowledge to take part. Only include statements to which you need the consumer to provide explicit consent.

Include a witness signature if required.

A witness is needed if the person giving consent cannot read. In signing this 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 the person giving consent.