# Participant Information and Consent Form

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| --- | --- |
| Short **Name of Project** | <Short name of project>  |
| Full Name of Project | <Full name of project> |
| Principal Investigator | <Principal Investigator> |
| Project Sponsor | <Project sponsor in Australia> |
| <Site Name> | <Name of site>  |



### What am I being invited to do?

We, <the project team>, invite you to take part in a project that <key research topic/question>. You have been invited to take part because <reason>.

If you take part, we will ask you to <provide a brief summary of what they need to do in the project>.

Around <number of people> will take part in this project. They will be from <hospitals/sites around Australia>.

Please read this information and ask us any questions. You can also talk to someone you trust, like a family member, friend, or your doctor. You can take some time to make up your mind. You get to decide whether this project is right for you.



### What is the purpose of this project?

In this project, we will <short description of what the project is about>.

[Include a brief description of project background, treatment, including whether it is approved by the TGA, and other relevant information. Keep this brief. Use short sentences and paragraphs.

If you need to provide more detailed information, provide it as supplementary information in the ‘where can I find out more information’ section. See the User Guide for details on providing supplementary information.]



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

**Taking part is up to you**

You get to decide whether you take part in this project. You can say yes or no.

Your decision will not affect your relationship <with your doctor> or <the hospital>.

<If you choose not to take part, your doctor will discuss other options with you>. These may include <relevant standard of care options>.

**You can change your mind at any time**

If you do take part, you can stop at any time. If you want to stop, please tell someone in the project team. You do not have to tell us the reason.

**[Option 1**:] Once you stop taking part, we will not collect any more information about you and will destroy the information we have collected about you.

**OR**

**[Option 2:**] Once you stop taking part, we will not do any more project visits. We will ask your permission to keep collecting information from your medical records. We will keep the information we have already collected about you. This is so we can measure the project results properly. Please only join this project if you are happy with this approach.

**The project might stop for other reasons**

We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the project if it is no longer in your best interests. If this happens, we will discuss this with you.



### What do I have to do if I take part?

If you take part in this project, you will be in it for <duration of project involvement>.

**Be aware that during the <relevant time period> you <must/must not> [Include here any restrictions, change in lifestyle, contraception, change of medication, etc specific to participation in the project.]**

This table below outlines what you need to do in this project. For more information, <please ask a member of the project team>.

[The table below can be changed as needed for your project. Remember to keep the explanations concise and relevant to the reader. Make sure to include:

* How the activity will be completed: online, in-person, by phone, etc.
* How long the activity will take
* A short description of what the activity involves
* Whether the activity is mandatory or optional
* Any particular requirements or access to intervention after the project finishes]

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| --- | --- |
| **What part of the project?** | **What do I have to do?** |
| When you start the project | [Include screening activities if relevant][Use the following text if the project is randomised.]If the project is suitable for you, you will be randomised. This means that you are put into a group by chance, like flipping a coin. We put people into groups and give each group a different treatment to see if one is better. You will have <an equal> chance of being placed in <either> group. [If project is double blinded, include the following] Neither you, your doctor, or the project staff will know what group you are in.You will be put in one of <2> groups: Group 1: <project intervention>Group 2: <a placebo, which is a medicine with no active ingredients>. |
| When you start treatment | [Include any activities when they start treatment, including optional activities to which participants may be asked to consent.] |
| During the project | [Include any activities during the project, including optional activities to which participants may be asked to consent.] |
| At the end of your project participation | [Include any post-trial access to drug/intervention] |
| After the project completes | We will send you a plain language summary of the results of the project.  |

Your time and expenses

[Delete this subheading and following text if it is not relevant to your project. Choose option 1, 2 or both below if this section is relevant.]

**[Option 1**:] You will need to spend <number of hours/days> in this project. To thank you for your time, we will give you <x amount of money and/or other item>.

**AND/OR**

**[Option 2:**] We will reimburse you for some of your out-of-pocket expenses while you are taking part in this project. We will reimburse you for <parking/meals/other>.

[Include information about the method and timing of payments or reimbursements.]



### What are the benefits of taking part?

By taking part, you will help the researchers understand more about <project topic>. This knowledge may help people in the future.

You <may/may not> directly benefit from taking part in this project.

[Include other potential benefits here, such as helping others or increased monitoring.]



### What are the risks and discomforts of taking part?

There are <no additional risks><potential risks> to you from taking part in this project.

[Tell the potential participant how the risks of taking part in this project differ from the risks they would face if they do not take part in the project. For example, if the risks are the same as standard care, you should make this clear.

Focus on the risks that are most likely to be relevant to the potential participant’s decision whether to take part. **These are likely to be those that are** **common, even if they are mild. They are also likely to be concerned about severe risks, even if they are rare.** Please see the user guide for more information about presenting risks.

Some suggested subheadings and section text can be found below. Delete any sections that are not relevant to your project and add any relevant risks that are not listed here. Further details about risks can be provided as supplementary information if needed, such as product information sheets.]

Risks of <project intervention>

[Delete this subheading and following text if it is not relevant to your project.]

All <medicines/devices> have side effects. The possible known side effects from <the intervention> are listed in the table below. <Most of the side effects are rare>. Some rare side effects may be serious. There may also be side effects that are unknown. Many side effects go away after you stop taking a medicine. Others can last a longer time or forever.

You should talk to a doctor urgently if you start to feel unwell during this project.

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| **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 will only experience these side effects in unusual cases |
| * <Side effect>
 | * <Side effect>
 | * <Side effect>
 |

Risks for unborn and newborn babies

[Delete this subheading and following text if it is not relevant to your project.]

<Name of medicine/intervention> is dangerous for unborn and newborn babies.

**OR**

**<**The effects of name of medicine/intervention> on unborn and newborn babies are unknown.

You cannot participate if you are pregnant, breastfeeding, or if you or a partner are trying to become pregnant. You should take action to avoid pregnancy while <taking medicine/ having intervention> and <for the following time frame>. This includes not donating sperm or eggs.

[If there are mandatory contraceptive or testing requirements include them here.] Tell us if you or a partner has conceived during this time frame so that we can help you manage any risks.

Risks if you are taking other medicines

[Delete this subheading and following text if it is not relevant to your project.]

There are some medicines and treatments that you cannot have while taking part in this project. You need to tell us about any medicines and treatments you are taking. These include:

* prescription medicines, such as antibiotics
* over-the-counter medicines, such a paracetamol
* vitamins or herbal medicines, such as echinacea
* alternative treatments, such as acupuncture.

We will tell you if you need to stop taking any.

Risks from exposure to radiation

[Delete this subheading and following text if it is not relevant to your project.]

[Insert a risk statement about exposure to ionising radiation as per local institution, HREC and state regulations.]

Chance of distress

[Delete this subheading and following text if it is not relevant to your project.]

The questions in the <questionnaire/survey/interview> may cover sensitive topics and this may cause you distress. If this happens, you can <take a break from/stop> the <questionnaire/survey/interview> at any time.

You can contact <support service> at any time by <calling support service number>. If you want, we can provide someone who is not part of this project team to give you support.

**Breach of confidentiality**

[Delete this subheading and following text if it is not relevant to your project.]

In this focus group, we will talk about sensitive topics. There is a chance that other people in the group could share information from the focus group with others outside of this project. We will remind everyone who takes part that they must keep what they hear in this focus group confidential and not share it with others.



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

[If your research project involves genetic and genomic research, consider whether the InFORMed template is right for you. For research that involves diagnostic or predictive genetic information, we recommend you use the [Australian Genomics consent forms](https://www.australiangenomics.org.au/tools-and-resources/research-consent-forms/).]

This section tells you how this project will collect, store, use, and share and/or dispose of your information <and samples>. If you do not want us to collect this information, you cannot participate in this project. If you would like to know more, see our <Data Management Plan/Privacy Policy/other document>.

**Collecting your information**

[Adjust the sources for collecting information as needed for your project.]

We will collect information for the project from <your medical record, local doctor/GP, and directly from you>.

[The statement and table below are for data linkage. Delete the statement and table if they are not relevant to your project. If relevant to your project, think about any information about the participant held by a third party that will be accessed by the project.]

We will also collect information from other services, which will be linked to information from this project. To correctly link different sources of data about you, we may need to use identifiers such your name, address, or date of birth.

We will only share your identifiers to accurately link information about you from different sources. For all other data sharing purposes, we will replace your identifiers with a unique code.

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| --- | --- |
| **Where will we collect your information from** | **What kind of information we will collect** |
| <Medicare, held by Australian Government> | <Your usage of health services> |
|  |  |

**Keeping your information <and samples> safe**

To keep your information <and samples> safe, we will:

follow all relevant privacy requirements

store information securely <at location> and/or <on an electronic database>

store <samples> securely at <location>

take steps to prevent anyone from accessing information <or samples> that identifies you unless they are authorised to do so, such as the project sponsor.

give information and samples a code and keep them separate from your name or contact information.

You can ask us to tell you what information we have collected about you as part of this project. If your information is not correct, you can also ask us to change it. If you have any complaints about how we are managing your personal information, you can <contact Privacy Officer>.

We will keep your information for <number of years>. We will keep your samples for <number of years>.

After this, <we will destroy the information and samples>

OR <we will destroy the information and samples unless you have agreed for them to be used for future research>

OR <we will permanently remove any information that directly identifies you but keep the deidentified information and samples>.

**Sharing your information with others**

[Delete this subheading and following text if it is not relevant to your project. This subheading should be used for any information sharing that will occur as part of the project. The next section deals with future sharing of information and samples. Consider if personal information will be sent overseas, and if so to which countries the information will be sent.]

We will share some of your information with these <people/organisations>:

* **Your <doctor/GP/other>**: we will tell your <doctor/GP/other> that you are taking part in this project. They <may/will> add this information to your medical records. If we find out information relevant for your ongoing care, we will share this information with your <doctor/GP/other> so you can receive the care you need.

**Analysing samples**: We <may/will> send your samples to <Australian laboratories to be analysed> AND/OR < laboratories in country A, B, C to be analysed. If sent overseas, your samples may not be covered by Australian laws>.

**Other parties if legally required:** by law, we may be required to share your information with others in certain circumstances. <In this project we will test for HIV and hepatitis. If results are positive, we will tell government health authorities>.

**Publishing project information**

We will share certain information from this project so that others can use it and understand the study findings. This project information <does not identify you individually/is limited to [data items] to make it hard to identify you>. We will make this project information available <through journal articles, presentations, and [restricted access/public] data repositories>. **By being in this project, you agree to us sharing project information for these purposes**.



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

[Delete this entire section and following text if it is not relevant to your project.]

Sharing your <individual/more detailed> data may help improve new research projects in the future. **We will also ask you to consider sharing your <individual/more detailed> data, <including your blood/tissue/other samples>, for ‘future research’**. When we share your <individual/more detailed> data <and blood/tissue/other samples>, we will take steps to make it difficult for anyone to link this data back to you. This includes removing information that could easily identify you, like your name or contact information. There is still a small chance that someone could identify you again.

[Choose the text in **either** Option 1 or Option 2 below. If potential participants cannot choose with whom their data will be shared, only if it will be shared at all, choose Option 1. If potential participants can provide different levels of consent for sharing data, choose Option 2 and edit the relevant options.]

**[Option 1:]** If you agree, we may share your <individual/more detailed> data <and samples> for research that is very similar to this project or research that is very different. The researchers may be in Australia or overseas. They may work for a commercial organisation like a pharmaceutical company or medical device company.

**OR**

**[Option 2**:] You can choose the kinds of research for which we share your <individual/more detailed> data <and samples>:

* Any future research

**OR** you can choose to allow access by research projects that are:

* related to this health condition
* being done in Australia
* being done by non-commercial organisations, like universities and public research institutes.

[Check that the above options match with the options you provide for consent on the signature page.] If you agree to share your <individual/more detailed> data <and samples>, you will not be told about the future research projects or any results from these projects. [If your project has capacity, include the following statement.] However, you will be able to see the types of research projects with which we have shared information and samples on our website.

If you change your mind, you have the option to ask us to stop sharing your <individual/more detailed> data <and samples>. However, if your <individual/more detailed> data <or samples> have already been shared, it may not be possible to retrieve or destroy them.

More information about how we will share your <individual/more detailed> data <and samples> for future research is in our <Data Sharing Policy/other document>.



### Who is running and paying for this project?

This project is being run by <name of site>

This project is being organised by <name of sponsor/CRO and/or other institution>.

The site is receiving funding from <institution/funding body/grant details> to run this project.

[List any relevant conflicts of interest here.]



### What happens if something goes wrong?

[This section may not be applicable for all types of research projects. Delete this entire section if you do not need it.]

In an emergency, you should call 000 or go to the emergency department at your nearest hospital. If your injury is not urgent, you should contact us. We can help you organise medical care.

[The following text is for **commercially sponsored** clinical trials.]

The sponsor of this project has agreed to follow the compensation process set out in the <Medicines Australia’s/Medical Technology Association of Australia’s> ‘Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial’.

[Link to the appropriate MA or MTAA Guidelines for participants to access as needed]

Under these Guidelines, you should be compensated for significant injuries you get from taking part in this project. <Project sponsor> will decide whether to pay compensation to you and how much you will get. You may also be able to take action through the courts. You may wish to seek independent legal advice. If you are eligible for Medicare, you can receive the treatment you need to treat the injury free of charge as a public patient in any Australian public hospital.

[The following text is for **non-commercially sponsored** clinical trials.]

If you are harmed because of taking part in this project, contact <Principal Investigator, contact phone number>. We will talk about treatment options with you and your doctor. You may also be able to take action through the courts. You may wish to seek independent legal advice. If you are eligible for Medicare, you can receive the treatment you need to treat the harm free of charge as a public patient in any Australian public hospital.



### Who has reviewed and approved this project?

The <name of ethics committee> has approved this project. This is an independent committee that makes sure that this project meets Australian ethical standards for research that involves people. <This form has been created/reviewed with><consumer group name>.

**Comments or complaints about how this project is being run**

If you have any comments or complaints about this project, please contact:

<Name> <Ethics contact> <Contact details>

<Name > <Complaints contact> <Contact details>



### Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

<Name > <Role> <Contact details, phone number preferred>

<Name > <Role> <Contact details, phone number preferred>

You can find out more information about the project by <visiting our website/scanning the QR code below/asking us> for:

* [List supplementary information here, using links if electronic]

[See User Guide for more guidance on providing supplementary information.]

# Signature Page

|  |  |
| --- | --- |
| Short **Name of Project** | <Short name of project>  |
| Full Name of Project | <Full name of project> |
| Principal Investigator | <Principal Investigator> |
| Project sponsor | <Project sponsor in Australia> |
| <Site Name> | <Name of site>  |

|  |
| --- |
| **Consent to take part in this project: This means you can say NO** |
| By signing this consent form, I acknowledge that:* I freely agree to take part in this project
* I understand that I can stop taking part in the project at any time
* I have read, or have had read to me, the information provided about this project and understand what is involved including the use of my personal information
* I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received

[If they apply to this project, include the following statements:]* <I agree to genetic testing as part of my taking part in this project>
* <I give permission for my medical records to be accessed for the purposes of this project>
 |
| **Consent to future use of information and samples** **[Delete section if not relevant]** | **Yes** | **No** |
| **[If using Option 1**] I agree to my <individual/more detailed> data and samples being collected, stored and shared for **any** future research | £ | £ |
| **OR** |  |  |
| **[If using Option 2]** I agree to my <individual/more detailed> data and samples being collected, stored and shared for * any future research

OR only these options: | £ | £ |
| * Research projects that are closely related to this one
 | £ | £ |
| * Research projects that are being done in Australia
 | £ | £ |
| * Research projects that are being done by non-commercial organisations
 | £ | £ |
| **Consent to optional parts of this project** **[Delete section if not relevant]** | **Yes** | **No** |
| I agree to <other optional aspects of participation, e.g. consent to videography, sub-project participation, etc> | £ | £ |

**Person taking part in the project**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**<Person conducting the informed consent discussion**

I have explained the research project, its procedures and risks to the potential participant and I believe they have understood that explanation.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ >

**<Witness (where decision-maker has required assistance to read this form)**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ >

Each person must sign and personally date this consent form