# Participant Information and Consent Form

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| --- | --- |
| Short **Name of Project** | Abbreviated 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.

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

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



### What is the purpose of this project?

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

Include description of project background, treatment (including whether it is approved by the TGA), health condition and other relevant information here. Keep this brief and make sure paragraphs are concise. Keep them to no more than 2-3 sentences. This is a good place to use diagrams or images to explain complex concepts.

If you wish to provide more detailed information, provide it as supplementary information. See the User Guide for details on providing additional 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 won’t affect your relationship with your doctor or the hospital. If you don’t take part, your doctor will discuss other options with you.

**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.

Once you stop taking part, we will not collect any more information about you. We will keep the information we have already collected to make sure the results of the project can be measured properly.

**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 interest. 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.

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 (e.g. online, in-person, by phone)
* How long the activity will take
* A short description of what the activity involves
* Any particular requirements or access to intervention after the study finishes

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| **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 a consent form. |
| When you start the project |  |
| When you start treatment |  |
| During the project |  |
| At the end of the project |  |

Payment for 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 hours/minutes of time taking part in this project. To recognise your time, we will offer you amount/other item.

**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.



### What are the benefits of taking part?

You may/may not directly benefit from taking part in this project. It is possible but unknown whether this intervention will help to potential benefit.

Include other potential benefits here.

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



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

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

Tell the consumer 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 consumer’s decision whether to take part. **These are likely to be those that are** **common (even if they are mild) or severe (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 (e.g., product information sheets).

Risks of taking [medicine]

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

All medicines 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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| --- | --- | --- |
| **Common side effects**One in 10 people will experience these side effects | **Rare side effects**One in 10,000 people will experience these side effects | **Very rare side effects**People will only experience these side effects in very 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/may be dangerous for unborn and newborn babies. You cannot participate if you are pregnant, trying to become pregnant or breast/chest feeding. There is also a risk from affected sperm that is used to conceive. Because of this, all participants should avoid pregnancy while taking medicine/having intervention and for the following time frame. Tell us if you or your partner have 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 133333. 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.



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

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/).

**Collecting your information**

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

Delete the following text if it is not relevant to your project. If relevant to your project, think about any access to information that might be provided to participants.

We will also collect information for this project from other services. The information will be linked to a unique code, also known as an identification number, that is created for you. We will not link your identification number to your name or contact information.

|  |  |  |
| --- | --- | --- |
| **Where will we get your information from** | **What kind of information we will get** | **Who is responsible for the information** |
| Medicare | Your usage of health services | Australian Federal Government |
|  |  |  |

**Keeping your information safe**

To keep your information safe, we will:

follow all relevant privacy requirements

keep it securely at location/on an electronic database

take steps to prevent anyone from accessing information that identifies you unless they need to, for example, to check it in an audit

give it a code and keep it separate from anything that could easily identify you, like 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.

We will keep your information for number of years. After this, we will destroy it/you can request that we destroy it/other relevant option.

**Keeping your samples safe**

Delete this subheading and following text if it is not relevant to your project. If relevant to your project, think about any access to samples that might be provided to participants.

We will keep your blood sample/tissue samples/other safe by:

keeping them securely at location

giving them a code and keeping them separate from anything that could easily identify you, like your name or contact information.

We may/will send your samples to international laboratories to be analysed.

We will keep any leftover samples that have not been used up in the project for number of years. After this, we will destroy them/you may request that we destroy them/other.

**Sharing your information with others**

Delete this subheading and following text if it is not relevant to your project. This section should be used for any information sharing required as a condition of participation. The next subheading deals with optional data and sample sharing. 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 others.

**Sharing information with your local doctor/GP/other**: we will tell your local 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 local doctor/GP/other so you can receive the care you need.

**Legal requirements to share your information**: some information needs to be shared with others by law. In this project we will test for HIV and hepatitis. If results are positive, we must tell government health authorities.

**Sharing information with other researchers:** we will share certain information from this project so that other researchers can use it in the future. These researchers may be in Australia or overseas. We will only share information that has been aggregated (that is, joined together with information from others before sharing/)/other strategy to ensure anonymisation.

**Getting more information**

If you would like to know more about how we will collect, store, and share your information and samples as part of this project, see our Data Management Plan/Privacy Policy/other document.



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

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

We will ask you to consider sharing your information, including your blood/tissue/other samples, for future research. Sharing information with others can help make all research more effective.

When we share your information and samples, we will take steps to make it difficult for anyone to link the information back to you. This includes removing information that could easily identify you, like your name or contact information. There is still a very small chance that someone could identify you again.

Choose the text in option 1 or option 2 below. If participants cannot choose with whom their data will be shared, choose option 1. If participants can provide different levels of consent for sharing data, choose option 2 and enter the relevant options.

**Option 1:** If you agree, we may share your information and samples for research that is very similar to this project or research that is quite different. The researchers may be in Australia or overseas. They may work for a commercial organisation like a pharmaceutical company or medical device company.

**Option 2**: You can choose the kinds of research for which we share your information and samples:

Any future research

Research projects that are related to this health condition

Research projects that are being done in Australia

Research projects that are 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 information and samples, you will not be told about the future research projects. However, you will be able to see the types of research projects with which we have shared information on our website.

If you change your mind, you have the option to ask us to stop sharing your information and samples. However, if your information or samples have already been shared, it may not be possible to retrieve or destroy them.

More information about how we will share your information is in our Data Sharing Policy/other document.



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

This project is being run by name of sponsor and/or other institution.

This project is being funded by institution/funding body/grant details.



### Who has approved this project?

The name of ethics committee has approved this project. This committee makes sure that this project meets Australian ethical standards for research that involves people.

**Complaints about how this project is being run**

If you have any complaints about how this project is being run, please contact:

Name Role Contact details



### 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. Note that all participants in Phase 1 and 2 clinical trials must be given access to a copy of the Medicines Australia (MA) compensation guidelines. For all other clinical trials, the Medicines Australia compensation guidelines should be made available on request. This can be provided in supplementary information.

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’.

Under these Guidelines, you should be compensated for significant injuries you get from taking part in this project. The 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.

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

If you are harmed because of taking part in this project, you may description of compensation options.



### 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 also visit our website/scan the QR code below/ask us to find more information about:

* List supplementary information here (use links if electronic)

See User Guide for more guidance on providing supplementary information.

# Signature Page

|  |
| --- |
| **Consent to take part in this project** |
| By signing this consent form, I acknowledge that:I freely agree to take part in this projectI understand that I can stop taking part in the project at any timeI have read, or have had read to me, the information provided about this project and understand what is involvedI have had the opportunity to consider the information, ask questions and am satisfied with the answers I receivedI agree to genetic testing as part of my taking part in this projectI give permission for my medical records to be accessed for the purposes of this project |
| **Consent to optional parts of the project** | **Yes** | **No** |
| I agree to my information and samples being collected, stored and shared for any future research | □ | □ |
| **OR** |  |  |
| I agree to my information and samples being collected, stored and shared for only: |  |  |
| 1. Research projects that are closely related to this one
 | □ | □ |
| 1. Research projects that are being done in Australia
 | □ | □ |
| 1. Research projects that are being done by non-commercial organisations
 | □ | □ |
| **Consent to optional parts of this project** | **Yes** | **No** |
| I agree to  | □ | □ |

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| --- | --- |
| Short **Name of Project** | Abbreviated 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  |

**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 participant and I believe they have understood that explanation.

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

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

**Witness**

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

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

Each person must sign and personally date this consent form