Insert your project logos. Refer to our [branding guidelines](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/).

|  |  |
| --- | --- |
| Short n**ame of project** | <Short, plain language project title>  |
| Full name of project | <Full name of project. Delete if not needed> |
| Principal investigator | <Title, name, position> |
| Project number | <[ERM number](https://au.forms.ethicalreviewmanager.com/Account/Login)> |
| <Site Name> | <Delete if not needed>  |

# Parent / Guardian Information and Consent Form



### What is my child being invited to do?

We are inviting your child to take part in a project that <key research topic/question>. They have been invited to take part because <reason>.

If your child takes part, we will ask them to <provide a brief summary of what their child needs 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 time to make up your mind. You get to decide whether this project is right for your child.



### 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 CTIQ User Guide for details on providing supplementary information.]



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

**Taking part is up to you and your child**

You get to decide whether your child takes part in this project. You can say yes or no.

Your decision will not affect your relationship with <The Royal Children's Hospital / Murdoch Children's Research Institute / other.>

<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 your child does take part, they can stop at any time. Simply tell someone in the project team. You do not have to give us the reason.

**[Option 1**:] Once your child stops taking part, we will not collect any more information about them. We will destroy the information we have collected about your child.

**OR**

**[Option 2:**] Once your child stops taking part, we will not do any more project visits. However, we will keep the information we have already collected about your child. 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 earlier than expected. If this happens, we will explain the reasons to you.

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



### What does my child have to do if they take part?

If your child takes part in this project, they will need to <provide brief summary of what the project involves>. You and your child will need to spend <X hours on this project / X months in this project>.

This section gives you more information about what your child will need to do.

<In the rest of this section, go into more detail about what the project involves. Use subheadings to break up the components of the project. You can also use tables and relevant visual aids. Depending on your study, this section could contain information about things such as screening, randomisation, study visits and procedures and so on. For further guidance, see the RCH [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document.

If your study is multi-site please consider other sites when providing these details. Make sure these details are correct for the participating sites and allow additions or deletions of information as needed.>

**a. Study visits**

<Your child will need to visit the <The Royal Children’s Hospital / Murdoch Children’s Research Institute / other> about <XX> times.> Explain what these study visits will involve and how long they will take. You can use sub-headings to explain the components of the study visits.>>

**b. Online survey**

<We will email you a survey about your child’s health. The survey will ask questions about XXX. It will take about 30 minutes to fill out.>

**Optional parts of this project**

<If your child takes part in this project we will ask you to think about letting us do a couple of extra things. The first is to let us <XX>. The second one is to let us <XX>.

You can say no to one or both of these things. If you say no, your child can still take part in the rest of the project.

Here is more information about what the optional consents involve.>>

**a. Optional consent: use of images**

<E.g. We are asking you let us use your child’s clinical photographs in this research. We would like to include these photographs in conference presentations and journal articles about our research. We will use these images to <XX>. Your child will not be identifiable in these images. We will protect your child’s privacy by <XX>. You can say no to this if you want to. If you say no, your child can still take part in the project.>

**b. Optional consent: contact about future projects**

<E.g. We are asking you to let us contact you about future projects about <XX>. If you say yes, we will contact you by <XX>. You can say no to this if you want to. If you say no, your child can still take part in the project.>

**During the <relevant period> your child <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 and your child need to do in this project.

[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]

|  |  |
| --- | --- |
| **What part of the project?** | **What does my child have to do?** |
| When your child starts the project | [Include screening activities if relevant. Otherwise, remove this section][Use the following text if the project is randomised.]If the project is suitable for your child, they will be randomised. This means they 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. Your child will have <an equal> chance of being placed in <either> group. [If project is double blinded, include the following] Neither you, your child, your doctor, or the project staff will know what group your child is in.Your child will be put in one of <two> groups: Group 1: <project intervention>Group 2: <a placebo, which is a medicine with no active ingredients>. |
| When your child starts treatment | [Include any activities when their child starts treatment. Include any optional activities.] |
| During the project | [Include any activities during the project. This includes any optional activities.] |
| At the end of your project participation | [Include any post-trial access to drug/intervention] |
| After the project finishes | We will give you a final letter that summarises the project results in plain language. |

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**:] Your child will need to spend <number of hours/days> in this project. To thank you for your time, we will give your child <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 your child is in this project. We will reimburse you for <parking/meals/other>.

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

**Project findings**

At the end of the project we will send you a final letter. This will explain what we found out in this project – in other words, our project results. The letter will not have any information specifically about your child.



### What are the benefits of taking part?

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

Your child <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?

<If your child takes part in this project, they may XX>

[Tell the parent how the risks of their child taking part in this project differ from the risks their child 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 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 your child starts to feel unwell during this project.

|  |  |  |
| --- | --- | --- |
| **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.

Your child cannot participate if they are pregnant, breastfeeding, or if they or a partner are trying to become pregnant. Your child 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 your child or a partner has conceived during this time frame. This is so we can help you and your child manage any risks.

Risks if your child is taking other medicines

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

There are some medicines and treatments that your child cannot have while taking part in this project. You need to tell us about any medicines and treatments they 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 your child needs 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. This may cause <you and your child> distress. If this happens, <you and your child> can <take a break from/stop> the <questionnaire/survey/interview> at any time.

We can also link <you and your child> in with support. <This will be free.>

**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. We will remind everyone they must keep what they hear in this focus group confidential. However there is a chance that other people in the group could share information with people outside this project.



### How will my child’s 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 child’s information <and samples>. If you do not want us to collect this information, your child cannot participate in this project. If you would like to know more, see our <Data Management Plan/Privacy Policy/other document>.

**Collecting your child’s information**

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

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

[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 about your child from other services. We will link it to information from this project. We may need to use identifiers to correctly link these different sources of information. These identifiers could include your child’s name, address, or date of birth.

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

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

**Keeping your child’s information <and samples> safe**

To keep your child’s 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 your child unless they are authorised to do so, such as the project sponsor.

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

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

We will keep your child’s information for <number of years>. We will keep your child’s 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 your child but keep the deidentified information and samples>.

**Sharing your child’s 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 child’s information with these <people/organisations>:

* **Your child’s <doctor/GP/other>**: we will tell your child’s <doctor/GP/other> that they are taking part in this project. They <may/will> add this information to your child’s medical records. If we find out information relevant for your child’s ongoing care, we will share this information with their <doctor/GP/other>. This is so your child gets the care they need.

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

**Other parties if legally required:** by law, we may be required to share your child’s 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 the findings. This project information <does not identify your child’s individually/is limited to [data items] to make it hard to identify your child>. 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 let us share the findings.**



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

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

**Sharing information**

To advance science, medicine and public health, we may share your child’s **deidentified information** with funders, research projects, biobanks, medical journals or data research repositories. Some of these organisations may be located overseas. **Any data that we send overseas may not be protected by Australian laws and regulations.** By signing this consent form you are giving us permission to do this.

If we share your child’s information, we will remove identifying details such as their name, date of birth and address. We will give this information a special code number. We will put security measures in place to prevent re-identification of your child’s identity. These security measures include <insert details>.

We will also put security measures in place to protect your child’s data if we transfer it to other people. We will <insert details about how their child’s data will be securely transferred>.

Despite our best efforts, there is a small chance that your child could be re-identified by someone outside of this research project. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that your child may have been re-identified, please let us know.

[For other data sharing options, refer to the [RCH Standard Wordings](https://www.rch.org.au/uploadedFiles/Main/Content/ethics/Standard%20Wordings%20June%202024.doc) document.]

**Future funding**

We may apply to government organisations or commercial companies for <more> funding for this project. If we get <more> funding, we may need to share your child’s deidentified information with the funder. If so, we will do this in a way that protects their privacy. We will also let you know that we have done this.

More information about how we will share your child’s <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 led. 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 child’s 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, your child should be compensated for significant injuries they get from taking part in this project. <Project sponsor> will decide whether to pay compensation to your child and how much they will get. You may also be able to take action through the courts. You may wish to seek independent legal advice. If your child is eligible for Medicare, they can get free treatment as a public patient in any Australian public hospital.

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

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



### Who has reviewed and approved this project?

This project has been approved by the Human Research Ethics Committee of The Royal Children’s Hospital in Melbourne. 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 the Director of Research Operations at The Royal Children’s Hospital and quote this reference number XXXX.

You can phone the Director on (03) 9345 5044 or email them at rch.ethics@rch.org.au.

[If relevant the following text is for a participating site to complete for a multi-site project.]

<If you would like to speak to someone at the site at which your child is participating please contact <position/name/phone number/email and quote this reference number XXXX>.



### Where can I find more information?

Thank you for taking the time to read this information. 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 number | <Project number> |

|  |
| --- |
| **Consent to take part in this project:**  |
| By signing this consent form, I acknowledge that:* I freely agree for my child to take part in this project
* I understand that my child 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 child’s 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 child taking part in this project>
* <I give permission for my child’s medical records to be accessed for the purposes of this project>
 |
| **Optional parts of this project** **[Delete section if not relevant. If you use optional consents, you must also explain them in the body of the consent form.]** | **Yes** | **No** |
| a. <Optional consent: use of images>  | £ | £ |
| b. <Optional consent: contact about future projects> | £ | £ |

**Participant’s name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Parent / guardian of the 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