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** | **Standard Wordings** |
| 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

This document gives you standard wordings that you can use in your participant-facing materials. These wordings are highlighted in blue.

Background information for researchers is highlighted in grey.

You can adapt the wording in this document to fit the needs of your project. However, you will see that some wordings have been approved by subject-matter experts, such as the RCH Human Research Ethics Committee, legal department, and IT department. If you would like to change these sections, please speak to us.

Icon

Description automatically generated

### 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.

Icon

Description automatically generated

### 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](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/ctiq.com.au/wp-content/uploads/InFORMed_User_Guide_Jun_24.pdf) for details on providing supplementary information.]

**Standard Wordings**

**TGA indications**

**TGA – approved for children in Australia**

The Therapeutic Goods Administration (TGA) Australia needs to approve medicines and medical devices before they are used for medical treatment. <Name of drug/device> isapproved in Australia to treat children with <condition>.

**TGA – approved for adults in Australia**

The Therapeutic Goods Administration (TGA) Australia needs to approve medicines and medical devices before they are used for medical treatment. <Name of drug/device> isapproved in Australia to treat adults with <condition>. It is **not** approved to treat children with this condition.

**Not approved by TGA, but approved internationally**

The Therapeutic Goods Administration (TGA) Australia needs to approve medicines and medical devices before they are used for medical treatment in Australia. <Name of drug/device> has **not** been approved by the TGA. However, it has been approved by <name of body> in <name of country>. The <name of body> has approved it to treat <children/adults> with <condition>.

**Experimental treatment – not approved**

<Name of drug/device> is an experimental treatment. This means that it is not an approved treatment for <condition> in Australia or other parts of the world.

**Experimental treatment – not approved for condition in question**

<Name of drug>isapproved by the Therapeutic Goods Administration (TGA) Australia to treat <other condition>. However, it is **not** approved to treat <condition>.Therefore, it is an experimental treatment for <condition>. This means it needs to be tested to see if it is a useful treatment for <condition>.

**Standard Wordings**

**Genes**

You have a set of genetic instructions that make you who you are. These are your genome. You can think of your genome as your book. Your genome can be broken down into smaller parts called chromosomes. These are the chapters in your book. Smaller still, are genes. These are the sentences in your book. Like a sentence, a gene has a beginning, middle and end. It contains information that shapes you. For example, your genes can determine the colour of your eyes and your blood type.

Each person has about 23,000 gene pairs. Genes are arranged along a chemical substance called DNA. Sometimes a gene message contains a ‘spelling mistake’. This can change the gene’s coded message. This gene change is also called a variation. If this makes the gene not work properly it is known as a mutation.

Many health conditions or diseases are caused by a change in one or more genes. These conditions may emerge at birth or may appear later in life. However, sometimes a gene can change without causing a health condition.

Genetic research involves testing and studying genetic material, usually DNA. Genetic research is done for many reasons including:

* finding out why some diseases run in families and how they are passed on from one generation to the next
* working out the chance of a future baby having a genetic condition
* working out possible environmental effects on genes – this is called imprinting
* learning about the cause of health conditions including cancers
* discovering more accurate ways of predicting disease in a group of people or where there is a strong family history of a disease.

**Standard Wordings**

**Cell lines**

In this project, we plan to create a cell line. This means we will take cells from a person’s blood and grow them in a laboratory. This will allow us to make an ongoing supply of cells to use for research.



### 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.>

**Standard Wordings**

**Puberty Status Assessment**

We will examine your child’s body for signs that they are sexually maturing. This may include checking for things like the:

* presence of pubic hair
* development of breasts
* development of testes.

In many cases we will be able to do a visual check.

If your child does not want a puberty status assessment, please tell us. We may be able to skip the assessment if you can give us information about your child’s sexual development.

**Standard Wordings**

**Pregnancy test**

If your child is able to bear children, they will need to have a pregnancy test to take part in this project. Your child will need to <insert details about pregnancy test. Use inclusive, gender-neutral language>. Your child cannot take part in this project if they are pregnant.

**Standard Wordings**

**Contraception**

Your child should not get pregnant or impregnate another person while they are in this project. This is because we do not know how the study drug affects an unborn baby.

If your child is sexually active, they must use an effective form of contraception while they are in this project. We can talk to you and your child about contraceptive options.

**Standard Wordings**

**MRI scans**

**This wording has been written by subject-matter experts. Please use it as is, or speak to us if you want to change it.**

We would like your child to have an MRI scan.

MRI is short for magnetic resonance imaging. The MRI scanner has a strong magnet. The magnetic attraction for some metal objects can pose a safety risk. It is important that metal objects are removed and not taken into the scanner room. You must tell us if your child has metal implanted in their body, such as a pacemaker or metal pins.

The MRI scanner is a large machine that is shaped like a big tube and is open at both ends. It has a bed to lie on and a head rest. The bed moves into the magnetic cylinder so that the part of the body that is scanned is in the centre.

Some important things to remember:

* Since the MRI machine is a big magnet, you must not take any metal into the scanner room. Before your child’s scan, we will ask you and your child to complete an MRI safety questionnaire. On the day of the MRI scan, one of the MRI technologists will go through the safety questionnaire again with you and your child.
* Before the scan your child will need to remove any metal accessories. This includes metal jewellery, hair pins, watches and so on. They may also need to remove make up, hair extensions or glitter. These items can interfere with MRI pictures.
* We will ask your child to lie on the bed. We will try to make sure they are comfortable.
* We will give your child some earphones. This is because the scanner makes loud knocking noises while it takes pictures. Your child can watch a video or listen to music during the scan.
* Your child needs to lie still while the pictures are taken.
* The scan will last [x] minutes.

We can organise a mock MRI session if you and your child want one. During a mock MRI, your child will spend time with an educational play therapist so they can become familiar with the MRI procedure. They will lie inside a ‘pretend’ MRI scanner that makes the same noises.

**For studies involving paediatric MRI on campus - delete if not applicable**

An experienced paediatric radiologist will review your child’s MRI scans. In the unlikely event that they find something that could be relevant to your child’s health, your child will have the option of being referred to the RCH Neurosurgery Research Clinic. The clinic will discuss your child’s scan with you. This will be at no cost to you.

**Standard Wordings**

**Using samples for future research**

**Storage and moving of deidentified data and samples for future research – mandatory**

We will store any deidentified data and samples that are left over from this project. If your child takes part in this project, we may store their deidentified data and samples at <institution name>. We may store them for an indefinite period. We will use a special ID number so your child’s name will not be attached to them. We will use these deidentified data and samples in future ethically approved research.

We may need to move your child’s deidentified data and samples to other locations. This includes overseas. We will make sure that we only send their data and samples to secure and ethically approved locations. However, **any deidentified data and samples that we send overseas are not protected by Australian laws and regulations.**

We will not contact you or your child to use the samples in future research.

You can only take part in this project if you consent to us sharing your child’s deidentified data and samples. **By signing this consent form, you agree to let us do this.**

**Or**

**Optional consent – Storage and moving of deidentified data and samples for future research**

We would like you to consider letting us store any deidentified data and samples that are left over from this project. If you let us do this, we will remove all personal identifiers from your child’s information, including their name, date of birth, address and UR number. We will put safeguards in place to prevent re-identification of your child’s identity. These safeguards include <insert details>.

If you give your permission, we may store your child’s deidentified data and samples at <institution name>. We may store them for an indefinite period.

We would like to use these deidentified data and samples in future ethically approved research.

We may need to move your child’s deidentified data and samples to other locations. This includes overseas. We will make sure that we only send their data and samples to secure and ethically approved locations. However, **any deidentified data and samples that we send overseas are not protected by Australian laws and regulations.**

We will not contact you or your child to use the samples in future research.

Please tick the appropriate box on the consent form to let us know if you consent to this.

**Standard Wordings**

**Statement for storage and use of sample/data in future research – tissue or data banks**

**Note to researchers**

**When tissue banks or data banks are being set up, the PICF must describe the following details:**

**• what sample/data is being kept for future research purposes**

**• where the sample/data is being stored**

**• what format the sample/data is stored. For example, is it coded? Explain that coded samples/data means that it can be re-identified**

**• what the sample/data will be used for. For example, for use in related research, that is, extended consent. Or for use in any type of research, that is, unspecified consent**

**• how long the sample/data will be kept for**

**• whether participants will be informed of future use of the sample/data**

**• if participants will be given the results of any future research using the sample/data**

**• if participants will be re-consented for the continuing use of their sample/data when they turn 18 years old**

**• if a sample is being stored, will additional data be kept with the sample**

**• if the sample/data is being sent overseas you must state that it will not be protected by Australian laws and regulation. This statement should be bolded.**

**Standard Wordings**

**Commercialisation**

Your child’s samples and other data may be used to help develop new medical tests, drugs or other commercial products. If this happens, you and your child will not be paid.

Your child’s samples and data will only be used for future ethically approved studies. However, is not possible to predict all the future uses of your child’s samples and data.

When we share your child’s samples and data, we will manage them securely and remove your child’s personal identifying information. However, there is still a risk that, in the future, your child’s samples and data may be traced back to them. We cannot predict how technologies will develop in the future, or how these developments may impact on your child’s privacy.

**Standard Wordings**

**Blood tests**

There are no major risks associated with a blood test. However, your child may feel some discomfort during the test. They may feel a sting when we put the needle in their arm. We can use a cream to numb the skin beforehand.

Your child may get some bruising, swelling or bleeding where the needle enters the skin. They may also feel a little light-headed when their blood is taken.

**Standard Wordings**

**Blood sample collection and consent to continue**

Due to the time-sensitive nature of this project, we collected a <insert volume> blood sample from your child when they arrived at <insert ward / department>. We took this at the same time as other blood samples for your child’s medical care. This minimised discomfort to your child.

We will now store the sample until we are able to discuss the project with you. We will ask you if you consent for your child to continue taking part in the project. You can say no if you want to. If you do not want your child to take part, we may destroy their sample as required by law. You can also tell us to destroy the sample at any time.

**Standard Wordings**

**Electronic study communication**

**This wording has been written by subject-matter experts. Please use it as is, or speak to us if you want to change it.**

**Text messages via third party platform**

As a participant in the study you will receive text messages from our research team. You may receive these messages via a third party communications platform. <Insert details about this platform in plain language>.

**Online scheduling platform**

You need to use an online appointment scheduling platform to book study visit appointments. You will be required to login to book and manage your appointment time for your clinic visit.

**Privacy re electronic communications**

To enable you to receive text messages and to manage your study appointments, we may transfer some limited personal information to the vendors of the third party platforms. This information could include your name and mobile phone number. The vendor may be located locally or in another country.

<We have chosen platforms that will be stored securely and processed in line with applicable data protection and privacy laws and regulations. Under the terms and conditions of the vendors of the relevant platforms, they are not permitted to share your personal information with any third parties. They can only use your personal information to communicate with you about study. **Note to researchers:** You can **only** include these three sentences if the RCH legal department and IT have confirmed that a. the platform is acceptable from a privacy and security perspective, and b. these three sentences accurately reflect the terms and conditions of the platform vendor.>

**Twilio**

If you would like text message reminders to your phone, your phone number will be transmitted to, and stored by, Twilio on servers located in the USA. **Once your information is transferred outside Australia, it is no longer protected under the Australian Privacy Act 1988 (Cth).** It will be subject to Twilio’s privacy policy, available at https://www.twilio.com/legal/privacy. It will also be subject to the privacy laws of the USA. The US laws may or may not offer an equivalent level of protection to the laws in Australia.

**Standard Wordings**

**Interview - camera must be on**

We will do the interviews online, using [Zoom / name of platform]. You must have your camera switched on for the entire interview. If you do not have a functioning camera, you cannot take part in the interview.

Note to researchers: We have had reports of participants who have done multiple research interviews to collect multiple payments. They have done this by leaving their cameras off for the interviews. This is why, as a general rule, we require participants to have their cameras on for their interview. However, if you may need to allow participants to have their camera off for the interview, please let us know the reasons for this.

**Recording your interview**

We will make an audio recording of the <interview / focus group>. This is so we can concentrate on what your child has to say.

We will keep this recording safe by <insert details of what you will do to protect confidentiality>.

After the <interview / focus group> we will transcribe the recording. This means we will make a full written copy of the recording. This will be done by <the research team / an external transcription service. If using an external transcription service, include confidentiality information>.

After we have finished with the recording we may securely destroy it as required by law. We will destroy it by <insert details>.

**Standard Wordings**

**Disclosing other treatments – for clinical trials only**

**Other treatment**

You need to tell us about any treatments or medicines your child is taking. These include:

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

You need to tell us if there are any changes to your child’s treatments or medications while they are in this project.

During the project, your child may not be able to take their usual medicines or treatments. We will tell you which ones they need to stop taking.

**Standard Wordings**

**Access to study drug / device**

**No access until TGA registration**

After the research project ends, the <drug / device> will not be available until it has been registered by the Therapeutic Goods Administration.

**Access via extension project**

Your child may be able to take part in an extension research project to continue taking the <drug / device>.

**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.>

**Standard Wordings**

**Access to Newborn Screening Card**

**c. Optional consent – access to Newborn Screening Card**

When your child was born, their healthcare workers collected a small sample of blood from them by pricking their heel. This sample was for testing for serious and treatable diseases. The healthcare workers collected four blood spot samples on a card called the ‘newborn screening card’. They sent this card to the Victorian Clinical Genetic Services (VCGS) laboratory for testing. After testing, VCGS stored the remaining blood spots.

We would like your permission to access your child’s newborn screening card. We want to use [X] of the remaining blood spots in this research project. We have ethical approval for this research project. VCGS will now allow us to access your child’s newborn screening card if we have your consent. VCGS makes sure they keep one complete blood spot in storage should it be needed for future medical reasons.

Please tick the appropriate box on the consent form to let us know if you consent to this.

**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.

A picture containing text, clipart

Description automatically generated

### 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.]

Icon

Description automatically generated

### 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.

**Standard Wordings**

**Genetic tests and risks**

**Genetic tests for research**

We are doing the genetic tests for research purposes. We will look at your child’s genes for features relevant to the research project.

**We will not give you the test results**. This is because we do not know how the results impact on your child. This means that the results would not change the way we care for your child.

**We can give you the test results**

You can decide whether you want to be told the genetic test result. It is important that you read the information about genetic test risks carefully so you can make an informed decision. If you decide to get the results, genetic counsellors can help you through the process. This will be free of charge.

**Genetic testing – issues for your child**

Genetic testing can raise important issues. If something is found in the genetic testing, you may need to tell your child about this in the future. For example, the test results may show that your child has an increased risk of developing a particular condition. This increased risk does not mean that they will actually develop the condition.

We are only searching for genes that are related to <condition>. However, it is possible that we may find genes responsible for other genetic conditions. If we find that your child has any genetic condition that you do not know about, we will contact you to discuss the findings. We will also refer you to a genetic counsellor. They will help you free of charge.

On rare occasions, we may find a change in your child’s genes that is unrelated to the research. We might not know if the change is important. However, if any changes are found, we will tell your doctor. They will discuss it with you, so they will manage your child’s health in the most appropriate way.

**Genetic testing – biological parent**

Genetic studies may incidentally reveal information about different family relationships such as a biological parent being different to a social parent. This finding will not be returned to you unless it is clinically relevant, in which case you will be referred to the appropriate care providers.

**Genetic testing – disclosing results to wider family**

Some people in your family might want to know about your child’s results. They may want to know whether the results have implications for them. You get to decide whether you want to tell them about the test results.

**Genetic testing – issues to think about**

If you decide to find out the results of your child’s genetic tests, this may have implications for them in the future. For example, they may need to tell third parties about these test results. These third parties could include insurance companies, employers, and financial or educational institutions.

Some people find it stressful to get information about their genetic make-up and future health. It is also possible that genetic information may be important in understanding the risks of having a child with <condition> in the future.

Your child’s participation in this project could raise personal issues for you. If this happens. we can refer you to a genetic counsellor. They will help you free of charge. We are also available to discuss any concerns you may have.

We will keep test results private but we cannot guarantee complete confidentiality. Because some genetic conditions are very rare, it may be possible to identify the test results.

**Standard Wordings**

**MRI risks**

**This wording has been approved by the RCH HREC. Please use it as is, or speak to us if you want to change it.**

MRI is short for magnetic resonance imaging. MRI scans are considered a safe procedure when performed at a centre with appropriate guidelines, such as <The Royal Children's Hospital / Murdoch Children's Research Institute / other>.

The MRI scanner has a strong magnet. The magnetic attraction for some metal objects can pose a safety risk. It is important that you remove metal objects and do not take them into the scanner room. This includes metal jewellery, hair pins, watches and so on. You **must** tell us if your child has metal implanted in their body. This could include a pacemaker or metal pins.

While it is operating, the scanner is noisy. Your child will wear earphones to protect their ears. The scanner is shaped like a long tube and may cause some people to feel cramped. Some people can feel anxious during the scan. If your child feels anxious we will stop the scan.

We are taking the scans for research purposes. They are not meant to be used to help diagnose, treat or manage your child’s medical condition.

After the MRI scan, a radiologist will look at the images for unusual features or unexpected findings. If the radiologist finds something that needs further examination, we will organise a referral to an appropriate medical doctor. The discovery of an unusual feature could have consequences for your child. It may affect their ability to work in certain professions or get insurance cover. However, the discovery of an unusual feature may also help your child get the treatment they need.

Please consider the pros and cons of discovering a health risk before deciding whether to let your child take part in this project.

**Standard Wordings**

**Anaesthesia risks**

**This wording has been developed by subject-matter experts. Please use it as is, or speak to us if you want to change it.**

**Anaesthesia risks**

Anaesthesia is generally very safe but there are some risks associated with it. The most common problems of anaesthesia are:

* feeling unwell
* vomiting
* bruising at the site of injections
* sore throat or hoarse voice.

Some children may be scared of and become upset by the procedure. Most people do not have these problems. If these problems do happen, they usually get better very quickly.

Anaesthesia can cause problems that are more serious where damage may be permanent. However, this is rare. Damage to the teeth is less common in children than in adults. The risk of brain damage or death due to anaesthesia is very rare.

The risk of problems from anaesthesia increases for people who:

* are having more major surgery
* have medical problems
* require difficult anaesthetic procedures.

If you have any concerns about these issues, you should discuss them with the anaesthetist looking after your child.

**Standard Wordings**

**Radiation risks**

**Note to researchers**

**All projects that include exposure to ionising radiation, even if it is standard of care, must be reviewed by an approved medical physicist. The medical physicist calculates the radiation dose for exposures that are above standard care and researchers will be given a recommended radiation risk statement that must be inserted into the PICF exactly as advised. Instructions on obtaining a medical physicist’s assessment is outlined in the** [**Radiation Safety in Research procedure**](https://www.rch.org.au/policy/policies/Radiation_safety_in_research/) **on the RCH intranet.**

Icon

Description automatically generated

### 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.

**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>.

**Standard Wordings**

**Data sharing**

**Note to researchers**

**Data format**

**The National Statement says that terms such as ‘identifiable’, ‘non-identifiable’ and ‘deidentified’ can be ambiguous. If you are using one of these terms in your PICF, you need to explain what it means in the context of your project. You can use the below definitions:**

**• Identifiable – We will store your child’s information with personal identifiers attached to it, such as their name, date of birth, address and UR number.**

**• Deidentified – We will remove all personal identifiers from your child’s information, including their name, date of birth, address and UR number. We will put safeguards in place to prevent re-identification of your child’s identity. These include [insert details].**

**• Re-identifiable – We will remove all personal identifiers from your child’s information, including their name, date of birth, address and UR number. We will replace your child’s name with a code number. Only the researchers who are working on this project will be able to re-identify your child by linking their code number to their name and other personal information.**

**• Non identifiable – We will not attach any personal identifiers or code numbers to your child’s data.**

**• Non re-identifable – The link between your child’s data and personal information is permanently deleted.**

**Protecting confidentiality**

**As a researcher, it is your responsibility to protect participants’ confidentiality in line with the relevant laws and regulations, as well as the terms set out in the PICF. For example, if you tell participants that their information is re-identifiable, you must remove personal identifiers such as the UR number. The UR number is considered identifiable information. This means that you should treat it as such, and avoid using it in other contexts, for example, as the participant’s study code.**

**Types of consent**

**• Specific consent: use of data collected for this research project only.**

**• Extended consent: use of data collected for this research project and for use in future related research.**

**• Unspecified consent: use of data collected for this research and for use in any future research.**

**Data sharing**

**The National Statement recognises that data sharing has become an important aspect of contemporary research. Increasingly, researchers are expected to make their data open, accessible and reusable. There are a number of reasons for doing this, such as increasing the transparency of the data and building trust in research. Most importantly, sharing data allows other researchers to build on your research, and potentially bring benefits to a greater number of people.**

**When you are designing your project, consider how you might make your data available for open access on data sharing platforms.**

**You may also be required to share your data with your funder, journals or other researchers. Typically, this data will be deidentified. Sometimes it will be re-identifiable.**

**Your PICF should include arrangements for data sharing unless there is a good reason not to. For example, there may be ethical considerations that apply specifically to your participants. This is particularly so if you are working with populations such as: women who are pregnant and the human fetus; people highly dependent on medical care; people with a cognitive impairment, an intellectual disability, or a mental illness; people who may be involved in illegal activities; Aboriginal and Torres Strait Islander Peoples; people in other countries or refugees.**

**You should also consider what data sharing agreements you have in place as part of your current funding arrangements and build these into your PICF. In addition, think about possible future funding arrangements. If you might be applying for additional funding in the future, consider adding a section into your PICF to cover future data sharing arrangements.**

**Data retention**

**As a researcher, it is your responsibility to determine the appropriate length of time for storing your project information. You should do this with reference to the particular requirements of your project as well as relevant laws, policies and guidelines. The below information is a guide only.**

**• If you are doing a short-term student project that is being completed for assessment purposes only, the general guideline is to retain the project data for 12 months after the completion of the project.**

**• If you are doing a clinical trial, the general guideline is to keep the project data for 15 years.**

**• If you are doing a project that involves gene therapy, the general guidelines is to keep the data indefinitely.**

**• If you are doing a project that has community / cultural / historical value, the general guideline is to keep the data indefinitely.**

Icon

Description automatically generated

### 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.]

**Standard Wordings**

**No financial gain**

Our researchers will not make money from your child’s participation in this project. Our researchers will simply receive their regular salary.

**Standard Wordings**

**Funding**

**Existing funding**

This project is funded by <insert names>. As part of our funding, we need to <insert any funding conditions that affect the participant>.

We will not pay you to take part in this research project.

**Future funding**

Currently, this research project is not funded. It is possible that we may receive funding from government organisations or commercial companies in the future. This funding would cover the costs of research. We will not pay you to take part in this research project.

If we get funding, we may need to share your deidentified information with the funder. If so, we will do this in a way that protects your privacy. We will also let you know that we have done this by sending you <an email / a newsletter / other>.



### 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.]

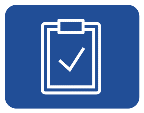
The sponsor of this project has agreed to follow the compensation process set out in the <Medicines Australia’s/Medical Technology Association of Australia’s> ‘Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial’.

[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?

The Royal Children’s Hospital HREC 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 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](mailto: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>.

Icon

Description automatically generated

### 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> | £ | £ |
| c. <Optional consent: access to Newborn Screening Card> | £ | £ |

**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