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

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Number:** | [Insert your [ERM number](https://au.forms.ethicalreviewmanager.com/Account/Login) here] | | |
| **Short Name of Project:**  **Full Name of Project:** | [Insert short plain language title of the project. Eg. Eye Tracks]  [Insert full title of the project. Eg. Using Eye Trackers to Diagnose Autism Spectrum Disorder in Children. If participants do not need the full title, delete this section.] | | |
| **Principal Investigator:** | [Insert academic title, name, position] | | | |
|  |  |  |  | |

Thank you for taking the time to read this **Participant Information and Consent Form**. We are inviting you to take part in a project about [briefly state what your project is about].

This form is [X] pages long. Please make sure you have all the pages.

**What is an Information and Consent Form?**

An Information and Consent Form tells you what the project involves. It helps you decide whether or not you want to take part in the project. Please read it carefully.

Before you make a decision, you can ask us questions. You may also want to talk to your family, friends or healthcare worker.

**Taking part in the project is up to you**

You get to choose whether or not to take part in the project.

If you decide you do not want to take part, this is ok. It will not affect your relationship with [The Royal Children's Hospital / Murdoch Children's Research Institute / other].

**Signing the form**

If you want to take part in the project, please sign the consent form at the end of this document. By signing the form you are telling us that you:

* understand what you have read
* had a chance to ask questions and received satisfactory answers
* consent to taking part in the project.

We will give you a copy of this Information and Consent Form to keep.

1. **What is the project about?**

We are inviting you to take part in a project called [insert short title of your project] (‘the project’). Our project aims to [tell the reader, in plain language, what you are trying to do].

[Summarise what your project is about and what they need to do in the project.]

[In the following sections of this PICF you will then give them a more detailed account of what the project involves.]

1. **Who is running the project?**

This project is being run by [insert names of institutions who are running the study / information about the study team].

It is being funded by [insert details].

It is taking place in [Melbourne / Australia / other].

[The Royal Children’s Hospital and the Murdoch Children’s Research Institute are research partners. In this project, they will work together by XXX. [Delete this section if only one research organisation is involved in your project.]]

1. **Why are we asking you to take part?**

We are asking you to take part in this research project because you are:

[outline the selection criteria for this project]

* [aged between XX and XX]
* [have XX]
* [are being treated by XX.]

1. **What do you need to do this project?**

If you take part in this project, you will need to [provide brief summary of what the project involves]. You will need to spend [X hours on this project / X months in this project].

This section gives you more information about what you 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 our [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document.]

**a. [Study visits – in person]**

[Your child will need to visit the XXX. [Explain what these study visits will involve and how long they will take.]

**b. [Study meetings – electronic]**

[Your child will need to take part in XX electronic study meetings. We will do these meetings online, on [name of platform]. [Explain what these meetings will involve and how long they will take.]]

**c. [Blood tests]**

[We will need to give your child three blood tests during this project. We will [give them details about when you will do these blood tests, how much blood you will take and so on.]

**Optional consents**

If you take 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 [XXX].

You can say no to one or both of these things and still take part in the project.

Here is more information about what the optional consents involve.

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

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

The following table illustrates what you need to do in this project.

**Table one: What you need to do in this project**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part of study** | **In-person or electronic?** | **How long will it take?** | **What does it involve?** | **Is it mandatory or optional?** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Can you withdraw from the project?**

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why.

[If you leave the project we will continue to use any information that we have already collected about you. Please only join this research project if you are happy with this approach. / If you leave this project, we will not use your information.]

[Insert further information about how you will treat/dispose of their information if they withdraw from the project. See our [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document.]

1. **What are the possible benefits for you and other people in the future?**

[We are doing this study for research purposes. Our aim is to progress our knowledge of [insert details], rather than to provide medical treatment to people with [insert details]. This means that the study will not directly benefit you. However, we hope that the research may help us provide better treatment for some people with [insert condition] in the future.]

[Or]

[We cannot guarantee that you will get any benefits from this project. However, there is a chance that you will be assisted by [insert details, e.g. closer than usual monitoring.]]

1. **What are the possible risks, side effects, and inconveniences?**

[See the [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document on our website for guidance on how to frame this section.]

[If you are offering any reimbursements, set them out in this section. See the Standard Wordings document for further guidance.]

1. **How will we keep your information confidential?**

We will collect and use your personal and health information for research purposes. [In this project, we will store your electronic information securely on an internal server. We will keep paper copies of your information in [insert details, eg. locked filing cabinet]. Your electronic and paper information will be stored at the [The Royal Children's Hospital / Murdoch Children's Research Institute / other].

These people may access your identifiable information:

* research team involved with this project, who will come from [The Royal Children's Hospital / Murdoch Children's Research Institute / other]
* RCH Human Research Ethics Committee
* [name of sponsor]
* [Therapeutic Goods Administration]
* [insert any other relevant names].

We will not share your identifiable information with anyone else except as required by law.

**Sharing information**

To advance science, medicine and public health, we may share your [**deidentified** / **re-identifiable** / [see our [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document for further guidance] data with any current and future funders, research projects, biobanks, medical journals or data research repositories. Some of these organisations may be located overseas. **Any data that we send overseas is not protected by Australian laws and regulations.** By signing this consent form you are giving us permission to do this.

If we share your data, we will remove identifying details such as your name, date of birth and address and give the data a special code number. We will put security measures in place to prevent re-identification of your identity. These security measures include [insert details].

We will also put security measures in place to protect your data if and when we transfer it to other people. We will [insert details about how the child’s data will be securely transferred].

Despite our best efforts, there is a small chance that you 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 you 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 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.

**Storage of information**

[Refer to the storage of information guidelines in our [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document]

1. **How will you find out the project results?**

[The RCH HREC expects that you communicate your study results to participants, where possible. See our [Standard Wordings](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) document for further guidance.]

1. **Who should you contact for more information?**

If you would like more information about the project, please contact:

|  |  |
| --- | --- |
| **Name:** | [insert name] |
| **Contact telephone:** | [insert contact phone number] |
| **Email:** | [insert email] |

In case of a medical emergency, you should call 000 or attend your nearest hospital’s emergency department.

For other urgent matters related to this project, please contact:

|  |  |
| --- | --- |
| **Name:** | [insert name] |
| **Contact telephone:** | [insert contact phone number] |
| **Email:** | [insert email] |

|  |
| --- |
| You can contact the Director of Research Operations at The Royal Children’s Hospital if you:   * have any concerns or complaints about the project * are worried about your rights as a research participant * would like to speak to someone independent of the project.   You can phone the Director on (03) 9345 5044 or email them at [rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au). |

**Consent Form**

|  |  |
| --- | --- |
| **Project Number:** | [insert ERM number here] |
| **Short Name of Project:** | [insert short plain language title] |

* I have read this information statement and I understand its contents.
* I understand what I have to do in this project.
* I understand the risks I could face because of my involvement in this project.
* I voluntarily consent to take part in this research project.
* I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
* I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
* I understand I will receive a copy of this Information Statement and Consent Form.

**Optional consent**

[Revise or delete if not applicable. If your project has optional consent options, make sure you have also explained them in the body of your PICF]

|  |  |  |
| --- | --- | --- |
| **a. Optional consent: [use of images]**  [I consent for identifiable images of my child to be used in conference presentations about this project] | I consent | I **do not** consent |
| **b. Optional consent: [contact about future projects]**  [I consent to be contacted about future research projects related to [condition name]] | I consent | I **do not** consent |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant Name |  | Participant Signature |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness to |  | Witness Signature |  | Date |

**Declaration by researcher:** I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Research Team Member Name |  | Research Team Member Signature |  | Date |

Note: All parties signing the consent form must date their own signature.