A picture containing text

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**Note to researchers:** This Example PICF shows you how to write your PICF in plain language. It is based on a fictional project that is very straightforward. Your project may be more complex and may require more detailed information.

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Number:** | 77777 | | |
| **Short Name of Project:**  **Full Name of Project:** | Eye Tracks  Using Eye Trackers to Diagnose Autism Spectrum Disorder in Children | | | |
| **Principal Investigator:** | Dr Angelica Azikiwe, Research Coordinator, Waratah Clinic | | | | |
| **Version Number:** | 2 | **Version Date:** | 01/06/2022 | | |

Thank you for taking the time to read this **Parent Guardian Information and Consent Form**. We are inviting your child to take part in Eye Tracks, a project about Autism Spectrum Disorder.

This form is 10 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 your child 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 your child takes part in the project.

If you decide you do not want them to take part, this is ok. It will not affect your relationship with The Royal Children's Hospital.

**Signing the form**

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

* understand what you have read
* had a chance to ask questions and received helpful 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 your child to take part in a project called Eye Tracks (‘the project’). The aim of the project is to test a machine that doctors can use to diagnose autism spectrum disorder (‘ASD’) in children. The machine we are going to test is called an eye tracker. It fits over a child’s head and is painless to use – see image one.

At the moment, doctors can lack the information they need to accurately diagnose ASD. This means that ASD is not detected in some children. These children can experience delays in getting the treatment they need. Other children might be incorrectly diagnosed with ASD – that is, a doctor thinks that a child has ASD when they do not. In both cases, it is important that doctors can quickly and accurately find out whether a child has ASD.

As part of the project, we want to test an eye tracker machine. We hope that this machine will allow doctors to diagnose ASD without having to use their personal judgment. The eye tracker is portable and easy to use. We hope it will be useful for children from different cultural and linguistic backgrounds. Potentially, this means that a broad group of children and their families may benefit from the eye tracker.

The eye tracker works by following the eye movements of a child who is looking at pictures of social scenes, such as people at a party. The eye movements of a child with ASD are different to those of a child without ASD. This means that a child with ASD who is looking at pictures of a party will have particular eye movements that our machine can pick up. The eye tracker machine measures a child’s eye movements to find out whether they have ASD and, if so, how severe it is.

The Therapeutic Goods Administration (TGA) Australia needs to approve medicines and medical devices before they are used for medical treatment. At the moment, the eye tracker machine is approved in Australia to use with adults. It is not approved to use with children. As part of this project, we want to register the eye tracker machine with the TGA so doctors in Australia can use it with children.

**Image One: Eye tracker machine**



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

The project will take place at the Waratah Clinic at the RCH.

It is being led by National Health and Medical Research Council, who are funding the project. They also wrote the protocol for this project. The protocol is a document that says what this project is about, and what it can and cannot do.

The project will run at a number of hospitals around Australia including the RCH. For this reason, the ‘research team’ for this project includes doctors and researchers at the RCH as well as Sunnybank Hospital in Brisbane, Jacaranda Hospital in Sydney, and Coodgee Hospital in Perth.

1. **Why are we asking your child to take part?**

We are asking your child to take part in the project because they are aged between six to 10 years and they:

* have had a longstanding diagnosis of ASD – that is, their diagnosis was made three or more years ago

**or**

* are a typically developing child.

1. **What does your child need to do in this project?**

If your child takes part in this project, they will need to do different things depending on whether they have ASD or are typically developing. This section gives you more information about what they will need to do.

**a. Children with ASD**

If your child has ASD they will have two in-person visits at the RCH and one electronic visit with a psychologist. They will need to spend **about three and a half hours** on this project. The visits are described in more detail in this section.

On your child’s first visit to the RCH, a doctor will give them a checkup. The doctor will measure their height and weight, and test their hearing and eyes. The doctor will also give your child some puzzles and pictures to take home. Your child will use these during their electronic visit with the psychologist. This visit to the RCH will take up to one hour.

If your child has ASD, they will speak to our psychologist. They can do this at home on a computer on a program called Microsoft Teams. The psychologist will ask your child about their:

• home life

• school

• interests

• friends.

The psychologist will watch your child playing with their favourite toys. They will also watch them using the puzzles and talking about the pictures that our doctor gave them. This will take about two hours. Your child can take breaks during this session if they need to.

On your child’s next visit to the RCH, they will use the eye tracker machine. The eye tracker machine is painless to use. A researcher will fit the machine over your child’s head. Your child will look at different pictures, such as children at a party, a child playing alone, and a family. The eye tracker machine will measure your child’s eye movements while they look at these pictures. This will take about half an hour.

**a. Typically developing children**

If your child is typically developing, they will have two in-person visits at the RCH. They will need to spend **about** **one and a half hours** on this project. The visits are described in more detail in this section.

On your child’s first visit to the RCH, a doctor will give them a checkup. The doctor will measure their height and weight, and test their hearing and eyes. This visit will take up to one hour.

On your child’s next visit to the RCH, they will use the eye tracker machine. The eye tracker machine is painless to use. A researcher will fit the machine over your child’s head. Your child will look at different pictures, such as children at a party, a child playing alone, and a family. The eye tracker machine will measure your child’s eye movements while they look at these pictures. This will take about half an hour.

Table One on the next page gives you more information about what this project involves.

**Table One: What the project involves**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Will your child complete these tasks?** | |
| **Part of study** | **In-person or electronic?** | **How long will this take?** | **What does this involve?** | **Child with ASD** | **Typically developing child** |
| **Medical check-up**  **All children** | In-person at the RCH | One hour | A doctor will give your child a checkup. The doctor will do the following things to your child:   * measure their height * measure their weight * test their hearing * test their eyes.   This will take up to one hour. | ✓  yes | ✓  yes |
| **Psychologist**  **Children with ASD only** | Electronic via Microsoft Teams | Two hours | A psychologist will speak to your child. They will ask your child questions about their:   * home-life * school * interests * friends.   The psychologist will also observe your child doing the following things:   * playing with toys * doing puzzles * describing pictures.   This will take up to two hours. Your child can take breaks if they need to. | ✓  yes | 🗶  no |
| **Eye tracker**  **All children** | In-person at the RCH | Half an hour | A researcher will fit the eye tracker over your child’s head. Your child will look at different pictures such as:   * children at a party * a child playing alone * a family.   The eye tracker will track your child’s eye movements while they are looking at the pictures. This is completely painless. If your child feels tired they can have a rest before continuing to use the eye tracker.  This will take about half an hour. | ✓  yes | ✓  yes |

**Optional consents**

**a. First optional consent: video use in presentations**

We are planning to present the findings of this project to medical staff and students, as well as other professionals who work with children who may have ASD. We want to show them footage of children using the eye tracker machine. This will give them a better idea of how children respond to the machine. For this reason, we are asking you to let us use your child’s video during our presentations. If you let us use your child’s video, your child **may be identified** by someone in the audience. We will not blur your child’s face as this interferes with people’s viewing of the eye tracker.

You can say no to this if you want to.

**b. Second optional consent: data linkage**

We will collect a lot of information during this research project. However, there are still lots of things about children with ASD that we do not understand. We could answer some of these questions by collecting information about your child from other organisations.

We would like your permission to let us link to information contained about your child in other databases. This additional information will help us get a better understanding of the similarities and differences between children with ASD and other children. If you agree to this, we will collect identifiable information about your child from the following databases or organisations:

* births, deaths and marriages register
* NAPLAN – this is an Australian program that tests skills such as reading, writing and numeracy
* Australian Early Development Census.

We will only use your child’s identifiable information in this research project. We will not share your child’s identifiable information.

You can say no to this if you want to.

1. **Can your child withdraw from the project?**

Your child 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 your child leaves the project we will keep using any information that we have already collected about them. Please only join this research project if you are happy with this approach.

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

We are doing this study for research purposes. Our aim is to progress our knowledge of ASD, rather than to provide medical treatment to children with ASD. This means that the study **will not** directly benefit your child.

However, we hope that the study will benefit other children with ASD. We hope that, in the future, the eye tracker will help doctors to more accurately diagnose ASD in children.

If your child participates in this study and has ASD, we will do a psychological assessment on them. This may give you a more accurate diagnosis of your child’s ASD.

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

The time that you and your child spend on this research project may inconvenience you both.

There is a risk that your child may become overly tired during this project. However, they can take breaks during the assessments if they need to.

The eye tracker machine is painless to use. However, if your child does not like having their head touched, they may become distressed when we use the machine on them. If this happens, we will try to soothe your child and give them a break if need be. If your child remains distressed, they can stop being in this project. If our project causes your child distress, we can refer them to psychological support. This will be free of charge.

There is a risk that the assessments will reveal new information about your child. For example, it is possible that you may find out that your child has been incorrectly diagnosed with ASD. If your child is considered to be typically developing, there is a small risk that you may find out that they have ASD. If either of these things happen, we will provide you with information about your options. We can also refer you on to appropriate treatment and support. Some of this treatment and support will be free of charge. However, some of these options may cost you money.

1. **How will we keep your child’s information confidential?**

We will collect and use personal and health information about your child for research purposes.

We may store your child’s identifiable information at the RCH. We will store your child’s electronic information securely on an internal server. We will keep paper copies of your child’s information in a locked filing cabinet in the Waratah Clinic.

These people may access your child’s identifiable information:

* research team involved with this project, who will come from the RCH, Sunnybank Hospital, Jacaranda Hospital, and Coodgee Hospital
* RCH Human Research Ethics Committee
* TGA.

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

**Sharing information**

To advance science, medicine and public health, we may share your child’s **deidentified 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 child's data, we will remove identifying details such as your child’s 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 child’s identity. These security measures include password encryption of your child’s information.

We will also put security measures in place to protect your child’s data if and when we transfer it to other people. After de-identifying your child’s data, we would safely share it with other researchers by use of a Virtual Private Network (VPN). A VPN is an online privacy tool that will keep your child’s data safe from everyone on the internet. However, there is still a small risk that your child’s information could be wrongly accessed by other people.

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 funding for this project. If we get 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.

**Storage of information**

We may keep the research project data for 15 years. The data may be securely stored at the RCH and the other hospitals that are taking part in this project: Sunnybank Hospital, Jacaranda Hospital, and Coodgee Hospital.

**Right to access information**

You have the right to access and correct the information we collect and store about your child. This is in line with relevant Australian and/or Victorian privacy and other relevant laws. Please contact us if you would like to access this information.

**Publicising results**

At the end of the research project, we may present the results at conferences. If you say yes to the letting us video your child using the eye tracker, we may share this video footage at conferences.

We may also publish the project results in medical journals. We will do this in a way that does not identify your child.

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

At the end of the project we will send you a final letter. This letter 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.

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

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

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

|  |  |
| --- | --- |
| **Name:** | Sam Davies, Researcher, Waratah Clinic |
| **Contact telephone:** | 9595 6666 |
| **Email:** | samdavies@royalchildhosp.org.au |

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

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

|  |  |
| --- | --- |
| **Name:** | Dr Angelica Azikiwe, Research Coordinator, Waratah Clinic |
| **Contact telephone:** | 9595 6667 |
| **Email:** | angelicaazikiwe@royalchildhosp.org.au |

|  |
| --- |
| 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:** | 77777 | | |
| **Short Name of Project:** | Eye Tracks | | | |
| **Version Number:** | 2 | **Version Date:** | 01/06/2022 | |

* I have read this information statement and I understand its contents.
* I understand what my child and I have to do in this project.
* I understand the risks my child could face because of their involvement in this project.
* I voluntarily consent for my child to take part in this 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**

|  |  |  |
| --- | --- | --- |
| **a. Optional consent: video use in presentations**  I consent for you to video my child using the eye tracker machine, and to use this video footage in presentations about the project. | I consent | I **do not** consent |
| **b. Optional consent: data linkage**  I consent for you to collect identifiable information about my child from the births, deaths and marriages register, NAPLAN, and the Australian Early Development Census. | I consent | I **do not** consent |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Child’s Name |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parent/Guardian Name |  | Parent/Guardian Signature |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness to Parent/Guardian’s Signature |  | Witness Signature |  | Date |

**Declaration by researcher:** I have explained the project to the parent/guardian who has signed above. I believe that they understand the purpose, extent and possible risks of their child’s 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.