|  |  |
| --- | --- |
| Short n**ame of project** | Eye Tracks  |
| Full name of project | Using Eye Trackers to Diagnose Autism Spectrum in Children  |
| Principal investigator | Dr Angela Azikiwe, Research Coordinator  |
| Project number | 97999 |

# Parent / Guardian Information and Consent Form



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

We are inviting your child to take part in a project called Eye Tracks. We are testing a machine that aims to diagnose autism spectrum disorder (‘ASD’) in children. This machine is called an Eye Tracker. It fits over a child’s head and is painless to use.

We want to test the Eye Tracker on both children who do, and do not, have a diagnosis of ASD. If your child takes part, we will ask them to wear the machine and look at pictures of things like people’s faces. We will also give them a medical checkup and review their medical records. If your child has an existing ASD diagnosis, they will also chat to our psychologist. Your child will need to spend around three and a half hours on this project.

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



### What is the purpose of this project?

ASD can be hard to diagnose, especially in children. Without a diagnosis, some children can miss out on the support they need. Other children might get diagnosed with ASD but they do not in fact have it. We want to find better ways to quickly and accurately find out whether a child has ASD.

Our project is testing the Eye Tracker – see image one. We hope the Eye Tracker will allow doctors to diagnose ASD without having to use their personal judgment. The Eye Tracker is portable and easy to use. We believe it will be useful for children from different cultural and linguistic backgrounds. Potentially this means that a wide range of children and their families could benefit from the Eye Tracker.

The Eye Tracker works by following the eye movements of a child who is looking at pictures such as people’s faces, or people talking at a party. The eye movements of a child with ASD are different to those of a child without ASD. A child with ASD who is looking at the pictures will have particular eye movements that our machine can pick up. The Eye Tracker 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. The Eye Tracker 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 with the TGA it can be used with children in Australia.

**Image one – Eye Tracker**





### 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 (‘RCH’).

**You can change your mind at any time**

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

If your child withdraws from the project, we will stop doing 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 talk to you.



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

If your child takes part in this project, they will need to visit the RCH two times. We will also review their medical records. If your child has an existing diagnosis of ASD, they will also have an electronic meeting with a psychologist.

We will also ask you to consider letting us use your child’s image in presentations and collect their data from other sources. These things are optional. They are explained in this form.

**a. Medical checkup – all children**

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 two hours.

**b. Psychologist – children with ASD only**

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 one hour. Your child can take breaks during this session if they need to.

**c. Eye Tracker – all children**

On your child’s second visit to the RCH, they will use the Eye Tracker. This is painless to use. 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, and a family. The Eye Tracker will measure your child’s eye movements while they look at these pictures. This will take about half an hour.

**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 use a video of your child in presentations. The second one is to let us collect information about them from other sources – this is called data linkage.

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.

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

We want to present the findings of this project to medical professionals who work with children who may have ASD. We want to show them footage of children using the Eye Tracker. 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**

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 are asking you to let us link to information we have about your child with the information 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 places:

* 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 not share your child’s identifiable information. You can say no to this if you want to.

**Table One: What your child needs to do in this project**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  | **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 | Two hours  | 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 | One hour | 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 |

Your expenses

If you take part in this project, we can help with your travel costs. We can reimburse the cost of parking at the hospital. Alternatively, we may be able to pay for the cost of public transport to the hospital. You will need to keep receipts for these expenses. If you are interested, please speak to us first.

**Project findings**

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



### What are the benefits of taking part?

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

Your child may not directly benefit from taking part in this project.



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

You and your child might be inconvenienced by the time you spend on this project.

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

The Eye Tracker is painless to use. However, if your child does not like having their head touched, they may become distressed. If this happens, we can give them a break. 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 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 will cost you money.



### How will my child’s information be used for this project?

This section tells you how this project will collect, store, use, and share and/or dispose of your child’s information. If you do not want us to collect this information, your child cannot participate in this project. If you would like to know more, we can show you our Data Management Plan.

**Collecting your child’s information**

We will collect information for the project from your child’s medical records and directly from you and your child.

You may also say yes to the optional consent for data linkage. If so, we will 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.

**Keeping your child’s information safe**

To keep your child’s information safe, we will:

follow all relevant privacy requirements

store information securely in a locked filing cabinet at the RCH or in a password protected electronic database

take steps to prevent anyone from accessing information that identifies your child unless they are authorised to do so, such as the project sponsor.

give your child’s information a code and keep them separate from their 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 the RCH Privacy Officer on 9333 4444.

We will keep your child’s information for 15 years. After this we will destroy the information.

**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.

**Publishing project information**

We will share certain information from this project so that others can use the findings. We have given you to the option of letting us use your child’s image in presentations to medical and other staff. If you say yes to this, your child may be identifiable.

We will also publish our findings in journal articles. These journal articles will not identify your child. We can give you access to the journal articles if you like.



**How will my child’s information be shared for future research?**

**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 measures are set out in our data security plan. We can give you a copy of this plan.

We will also put security measures in place to protect your child’s data if we transfer it to other people. We will only share your child’s data through a secure platform called OneDrive. We will never share your child’s data by email.

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.



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

This project is being led, and funded by, by the RCH.



### 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 reviewed by Autism Support Australia.

**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 34234.

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



### 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.

Dr Angela Azikiwe Research Coordinator 9333 3333

Pamela Mead Researcher 9333 3334

# Signature Page

|  |  |
| --- | --- |
| Short n**ame of project** | Eye Tracks  |
| Full name of project | Using Eye Trackers to Diagnose Autism Spectrum in Children  |
| Principal investigator | Dr Angela Azikiwe, Research Coordinator  |
| Project number | 97999 |

|  |  |
| --- | --- |
| Short **Name of Project** | Eye Tracks  |
| Full Name of Project | Using Eye Trackers to Diagnose Autism Spectrum in Children  |
| Principal Investigator | Dr Angela Azikiwe, Research Coordinator |
| Project number | 97999 |

|  |
| --- |
| **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
 |
| **Optional parts of this project**  | **Yes** | **No** |
| a. First optional consent: video use in presentations | £ | £ |
| b. Second optional consent: data linkage | £ | £ |

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

**Parent / guardian of the person taking part in the project**

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

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

Each person must sign and personally date this consent form