

PARENT/GUARDIAN INFORMATION STATEMENT

Could “Gazefinder” Eye-Tracking Technology Support the Earlier Identification and Diagnosis of Autism in Young Children?

Dr Kristelle Hudry, Lacey Chetcuti, Dr Cathy Bent, Dr Cherie Green, Dr Jodie Smith, Alexandra Aulich (LTU)
Prof. Andrew Whitehouse, Alena Clark, Diana Tan, Erica Fay (TKI)

What is this study about?

We invite you to have your child take part in a research project testing whether “Gazefinder” eye-tracking technology could improve our ability to detect and diagnose autism in early childhood. To achieve this, we need the help of young children with autism and young children who have no developmental difficulties or close family members with autism.

Who is conducting and funding this study?

This study is being run by a team of researchers in Melbourne and Perth. The Melbourne-based team is at La Trobe University (LTU), led by Dr Kristelle Hudry who is a Psychologist and Senior Researcher. The Perth-based team is at the Telethon Kids Institute (TKI), led by Professor Andrew Whitehouse who is a Speech Pathologist and Head of the Autism Research Team. The study is funded by the developer of Gazefinder: JVCKENWOOD Corporation (Japan). Under contract with the funder, researchers at LTU and TKI have the right to publish results arising from this study, but will have no rights or shares in any possible future commercial returns on the sale/use of Gazefinder as a clinical/diagnostic instrument. Funding for this study is also not contingent upon achieving specific results.



Does my child have to participate?

Being part of this study is voluntary. Where possible, when deciding if you want your child to take part, we ask you to discuss this with your child and decide together. We also ask you to read the information here carefully and ask any questions before deciding, or during study participation. If you decide not to be involved, this will not affect your relationship with LTU or TKI or any services your child may be receiving.

Who can participate?

Children can participate in this study if they fall into one of two groups:

Children with autism

- ✓ Age 2 years to 4 years 11 months
- ✓ No significant visual or hearing impairment
- ✓ Have a diagnosis of Autism Spectrum Disorder (ASD), with supporting documentation (i.e., letter or report from a medical/allied health professional)

Children without autism

- ✓ Age 2 years to 4 years 11 months
- ✓ No significant visual or hearing impairment
- ✓ No diagnosis or concerns about autism or other developmental, genetic, or neurological condition
- ✓ No sibling or parent who has autism

What does the study involve? If you decide together for your child to take part in this study...

For children with autism, we will:

1. Ask you to complete some questionnaires about your child’s development and skills, and provide family background information. These will take around 1 hour to complete and we can provide in advance of the face-to-face session, if you would prefer to complete these in your own time at home.

PARENT/GUARDIAN INFORMATION STATEMENT

2. Have your child attend a face-to-face assessment session at the University/Institute to complete play-based developmental assessments. We expect this should take 1½ hours, but can provide breaks and/or complete tasks across more than one session if your child needs more time. Please note:
 - We would ask your permission to video-record the developmental assessments to make sure our teams are running the activities consistently across our Melbourne- and Perth-based sites;
 - If your child has recently completed these developmental assessments (e.g., as part of another study), we may ask your permission to access these prior results to avoid unnecessarily re-assessment.
3. Have your child view the Gazefinder animation (noting that we do not need to video-record this activity).

For children who do not have autism, we will:

1. Ask you to complete some questionnaires about your child's development and skills, and provide family background information. These will take around 1 hour to complete, in your own time and return to us.
2. Review your questionnaire responses to confirm your child has the necessary level of social-communication skills to provide a good point of comparison to the children with autism. If your responses suggest your child has not yet reached such as level, your child will not be required for further assessment.
3. (For children who do meet the eligibility criteria for this group) Have your child attend one very short face-to-face session at the University/Institute to view the Gazefinder animation (no video-recording required).

Some further notes on Gazefinder:

Viewing Gazefinder takes only 2½-minutes and is like watching a computer or TV. Children sit on a small chair (or carer's lap). An initial scene shows animations popping up on different parts of the screen, to check Gazefinder can automatically detect where the child is looking.

The video animation is then shown, and includes clips that are playful and engaging for young children – animated characters, shapes, and human faces, set to a musical background and sound effects.

There are no instructions for children to respond in any particular way; they can just sit comfortably and watch the videos.



What are the benefits of being involved?

There will be *no direct benefit* for you or your child from participating in this study. We will not offer any payment and cannot give individual feedback from the Gazefinder assessment, as this is a new approach not previously tested. Given the study aims to see whether Gazefinder could support the detection and diagnosis of autism in young children, your child's involvement may help improve the diagnostic experience of *other* children and families in the future. We will certainly share results with you when the study is finished.

Are there any risks?

We have no reason to believe viewing Gazefinder presents any risk to your child; the low-powered light that tracks where children are looking is completely safe for the human eye. If your child experiences something you are not sure about, please contact us immediately so we can discuss the best way to address your concerns. Further, if completing questionnaires or other assessment activities does raise concerns about your child's development – in either group – we can discuss suitable professionals/services in your local community who you could make contact with.

What will happen to information about my child?

We will **collect** information about your child in a way that does not reveal *who* they are to anyone but the research team. Your child will be assigned a code, with all information collected labelled with this code (*not* his/her name). We will never share identifying information (e.g., names, video) of children when publicising our results.

PARENT/GUARDIAN INFORMATION STATEMENT

We will **store** your child's paper-copy information in a locked filing cabinet and enter information from forms onto a secure online database accessible only by the research team. Your child's eye-tracking data is automatically captured and stored by Gazefinder. We will copy this to a University/Institute computer and online database.

We will **present** the results of this study widely – including in peer-reviewed scientific journals, at local and international conferences, and shared with you and the general public (e.g., via traditional and social media).

We will **share** the *anonymous* data of all participants with JVCKENWOOD Corporation and another independent organisation, Pricewaterhouse Coopers. Together, these companies will conduct an independent analyses and prepare a report for submission to the Therapeutic Goods Administration (TGA). TGA approval is required if JVCKENWOOD Corporation wants to market Gazefinder for clinical/diagnostic use in the future, in Australia. Data stored on Gazefinder cannot be deleted and JVCKENWOOD Corporation have the irrevocable, perpetual right to use this to inform improvements to the device.

We will **keep** all data for at least 15 years after the study is finished, and archive the anonymous data file with a University Research Repository. After this time we will destroy your child's data. Storage, transfer and destruction will be in accordance with the Research Data Management Policy <https://policies.latrobe.edu.au/document/view.php?id=106/>. Personal information you provide will be handled in accordance with applicable privacy laws. Any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your child's personal information by contacting the research team.

Will my child and I be able to hear the results of the study?

We can email or post a summary of the results to you, once the study is finished.

What if my child and I agree to participate, but then change our minds?

You have the right to withdraw your child's participation from this study at any time, without question. You can let us know by completing the "Withdrawal of Consent Form" or notifying the team (details below) that you "*wish to withdraw your consent for your child's data to be used in this project*". The decision to withdraw participation at any point will *not* affect your relationship with LTU or TKI or any services your child may be receiving.

After withdrawing, we will not ask you or your child to provide any more information. Any *identifying* information we had collected – such as names and addresses – will be destroyed, and not retained for this study or stored future contact. We will retain any *de-identified* information (i.e., labelled with your child's code) that has already been collected up to the point of withdrawal, including any eye-tracking data captured by Gazefinder.

Who can I contact for more information?

If you have any questions or would like to express interest in having your child participate in this study, please contact the study leader at your relevant site:

Melbourne

Lacey Chetcuti
La Trobe University

✉ L.Chetcuti@latrobe.edu.au
☎ (03) 9479 5649

Perth

Alena Clark
Telethon Kids Institute

✉ Alena.Clark@telethonkids.org.au
☎ (08) 6319 1690

What if we have a complaint?

If you or your child have a complaint about any part of this study, please contact:

| Ethics Reference Number | Position | Telephone | Email |
|-------------------------|--------------------------------|-----------------|----------------------------|
| HEC19027 | Senior Research Ethics Officer | +61 3 9479 1443 | humanethics@latrobe.edu.au |