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PARTICIPANT INFORMATION SHEET

PLEASE RETAIN THIS INFORMATION SHEET FOR FUTURE REFERENCE

Project title:	**Using eye movements to measure vision in children:** objective assessment of visual performance using optokinetic nystagmus
Study site investigator: (site-specific)	Dr. Shuan Dai Ascot Hospital 90 Green Lane East, Remuera Auckland, New Zealand Telephone: +64 9 520-9689
Lead investigator:	Dr. Jason Turuwhenua Auckland Bioengineering Institute (ABI) School of Optometry and Vision Science Telephone: +64 9 923-1742
Project co-ordinator:	Dr. Lily Yu-Li Chang Auckland Bioengineering Institute (ABI) School of Optometry and Vision Science Telephone: +64 9 923-1689

About the Researchers:

This is an international multi-centre study led by the School of Optometry and Vision Science at The University of Auckland, in collaboration with Retina Foundation of the Southwest, Texas, USA. The principal Investigator is Dr. Jason Turuwhenua (Auckland Bioengineering Institute and School of Optometry & Vision Science, University of Auckland). The co-investigators are Dr. Shuan Dai (paediatric ophthalmologist), Associate. Professor Ben Thompson (vision scientist, University of Waterloo), and Professor Eileen Birch (vision scientist, Retina Foundation of the Southwest, Texas, USA). Dr. Peng Guo (Bioengineer) and Dr. Lily Yu-Li Chang (project co-ordinator), are postdoctoral research fellows in the Auckland Bioengineering Institute, University of Auckland.

We are inviting your child to participate in our study to test a new technique for vision testing in children.

Whether or not your child takes part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care your child receives.

This participant information sheet will help you decide if you would like your child to take part. It tells you why we are doing the study, and what is involved, so that you can make an informed decision about whether you would like your child to participate. You do not have to decide today whether or not you want your child to participate in this study. Before you decide, you may want to talk about the study with other people, such as family, friends, or healthcare providers. We encourage you to do this.

If you agree to have your child take part in this study, you will be asked to sign the Consent form on the last page of this document. You will be given a copy of this document to keep.

What is this study about?

This project is funded by the Ministry of Business, Innovation and Employment, New Zealand. It is driven by researchers at The University of Auckland. The purpose of the project is to develop an easy-to-use device that could help eye doctors and optometrists better measure visual function in children. It is based on measuring a naturally occurring eye movement called optokinetic nystagmus (OKN), an eye motion that occurs when people watch continuously moving patterns.

What does the study involve?

We are inviting 200 children from 3-6 years of age to take part in this study, 100 from Auckland, New Zealand and 100 from Dallas, Texas. Participants with current eye diseases other than focus problems, or developmental delay are not eligible for this study. If you wish to let your child take part in this study, you must agree to be informed of any incidental findings about your child's health. If an eye disease is diagnosed after eye movement data has been collected from your child, it will be retained for a separate analysis.

As part of your child's participation, we will ask you some demographics questions about your child. If your child is referred to our study by an eye doctor, relevant information from your child's eye examination will be provided to us by the referring doctor.

The first part of the study involves testing your child's vision with a standard letter chart. After this, your child will be asked to participate in a study where he/she will be shown various patterns on a television screen, whilst seated comfortably. If your child wears glasses or contact lenses, this testing will be done with or without these lenses. Your child will be asked to look at the screen and watch a children's movie. A moving pattern will be presented instead of the movie for short periods of time. Your child will be asked whether the moving pattern is going to the left or right, and can either answer directly or use hand gestures to signal the direction.

During the study, your child's face and eyes will be video recorded, with the intent of capturing his/her eye movements. Small stickers may be placed on your child's face as reference points. This assessment could take up to thirty minutes to complete, and your child will have the opportunity to have a break at any time.

Analysis of video recordings will be used to help us track your child's OKN eye movement. This data will be used for comparison with other people who take part in this study and will be

used to test whether the eye movement measure is as good as the eye chart measure for detecting vision problems.

Conflict of Interest

Data collection will be done with a prototype device developed by Objective Acuity Ltd, a UniServices (University of Auckland) start-up company co-founded by Lead investigator, Dr. Jason Turuwhenua, and Associate Professor Ben Thompson. The results will help the researchers validate this study device and method of vision testing. While there is commercial benefit for Objective Acuity Ltd and its founders, the intellectual property behind the study device is owned by The University of Auckland.

Benefits and Risks

Your child will have their visual acuity measured as a result of this study. Koha or compensation will be provided in the form of a $10 voucher **(site-specific)**. This study is registered as a clinical trial, and a brief summary of the study outcome will be sent to you by email if you indicate your interest on the consent form.

There are no specific risks involved with this project, and the methods we use are non-invasive. If for any reason you or your child feels any discomfort during the experiment, please inform the researcher immediately.

Compensation **(site-specific)**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

What happens to the information collected from your child?

The paper records will be stored in a locked cabinet of an access-controlled office in The University of Auckland. Electronic files such as video recordings and forms will be stored on a password-controlled computer network and drives. All information is stored securely for 6 years after the study ends. Your child's name will only appear on the attached Consent Form, which will be coded with an identification number. This identification number and your child's initials will be used throughout the study. Access to any participant information will be restricted to the researchers directly involved in this project.
The video recording and information we extract from it (e.g. speed and size of your child's eye movement) will not be provided to participants.

Right to withdraw from participation

Participation in this study is entirely voluntary, and if you choose to let your child participate, you can change your mind at any time without giving a reason.

After your child's participation is completed, you will still have the right to request that the data be withdrawn from the study up to one month after your child's participation.

Confidentiality

Personal identifiable information will be kept confidential. In published work and conference presentations any information collected from your child will remain anonymous. We may include your child's image or video in a research presentation, but only with your consent (as indicated on the Consent Form).

Who do I contact for more information or if I have concerns? (site-specific)

Dr. Shuan Dai
Ascot Hospital
90 Green Lane East, Remuera, Auckland, New Zealand
Telephone: +64 9 520-9689

If you want to talk to someone who isn't working on the project, you can contact a health and disability advocate on:

Phone:	0800 555 050
Email:	advocacy@hdc.org.nz

For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142.
Telephone 09 373-7599 ext. 83711.
Email: ro-ethics@auckland.ac.nz

This study was approved by the University of Auckland Human Participants Ethics Committee on 04-Jan-2017 for three years, Reference Number 018420.

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CONSENT FORM

THIS FORM WILL BE HELD FOR A PERIOD OF SIX YEARS

Project Title: Using eye movements to measure vision in children

(objective assessment of visual performance using optokinetic nystagmus)

- I have read and understood the Participant Information Sheet.
- I have had the opportunity to ask questions and have them answered to my satisfaction.
- I agree to let my child take part in this study.
- I understand that I can ask for the video recording to be stopped at any time.
- I understand that I am free to let my child withdraw participation at any time and to withdraw any data traceable to my child up to one month after his/her participation is complete.
- I understand that the results of this work may be used in publications and conference presentations, and that my child's personal details will remain confidential. Images and video will remain confidential unless I have given consent for them to be used.
- I understand participant's data will be kept for six years after study completion.
- I agree that I will be informed of any incidental findings on my child

I agree that images that may include my child's face could be part of future research outputs beyond this study.	Yes ☐	No ☐
I would like a brief summary of study outcome at the end of this study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this trial.

Participant's name: _____

Parent/guardian's name:_____

Email: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the study to the participant's parent/guardian, and have answered question(s) about it.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

I will ensure a copy of the Participant Information Sheet and Informed Consent Form is provided to the participant.

Researcher's name: _____

Role in project: _____

Email _____

Signature _____ Date _____