

Participant Information Sheet

Title	Evaluation of ACO Eye Health patient records for accessibility, eye conditions, and care provision to the Victorian community.
Short Title	Understanding eye care needs in Victoria.
Protocol Number	University of Melbourne Human Research Ethics Committee application: 32344
Principal Investigator	Dr Timothy Fricke
Associate Investigator(s)	Dr Josephine Li, Dr Katerina Kiburg, Dr Ling Lee, Dr Erica Barclay, Dr Laura De Angelis
Locations	Carlton (Main Clinic) 374 Cardigan Street, Carlton, 3053 Braybrook Clinic 107-139 Churchill Avenue, Braybrook 3019 Coolaroo Clinic 1550 Pascoe Vale Road, Coolaroo, VIC 3048 Dandenong Clinic 116 David Street Dandenong 3175 East Reservoir Clinic 125 Blake Street Reservoir 3073 Frankston Clinic Gate 1, Building L, 2 Hastings Road Frankston 3199 Knox Eye Care 520 – 538 Mountain Highway, Bayswater 3153 Wyndham Eye Care 31 Heaths Road Hoppers Crossing 3029

Part 1 What does my participation involve?

1 Introduction

You, your child or person you are caring for, are invited to contribute to ongoing research at the Australian College of Optometry (ACO) and National Vision Research Institute (NVRI) because you have had at least one eye examination at one of the ACO Eye Health clinics.

This Participant Information Sheet tells you about the purposes of the research and what is involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read the form carefully to understand your rights and how your information will be used responsibly. You are welcome to contact us to ask questions about anything that you don't understand or want to know more about. Before deciding whether not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide NOT to take part in the research, you can either sign the withdrawal section or notify the ACO staff or research team. Unless you formally withdraw, your de-identified data may be included in the research. This Participant Information Form is available for you to keep.

2 What is the purpose of this research?

Whenever someone visits the clinic for an eye test, information is collected about them and stored in our secure system. This is called an eye test record, and is used by our optometrists to deliver eye care to you (or your child, or someone you care for). It includes basic information about the person visiting for an eye test, such as name, date of

birth and address, health information such as medical conditions, and the results of any tests done as part of the eye examination. We also collect information about why the individual is eligible for our eye test services or discounted spectacles. We call all of this information 'routinely collected' because it is necessary for the eye care we deliver, and how that care is funded.

Researchers can use routinely collected information from eye test records to increase our understanding of eye diseases, and to improve eye care. Because this is a different use of the information you have provided to allow us to deliver your clinical care, this can only be done with approval from a research ethics committee, to make sure the research is necessary, ethical and culturally sensitive.

This research aims to better understand eye conditions and identify trends and clinical outcomes of patients provided services through the ACO by using eye test records. In particular, we are interested in investigating refractive errors (common eye conditions which can be helped with glasses), binocular vision (how the two eyes work together), common eye diseases (such as cataracts, glaucoma, aged-related macular degeneration and diabetic retinopathy), the impact of subsidised visual aids, and care pathways between the optometry and other services.

This information can guide future improvements in clinical outcomes by providing evidence to improve eye care delivery and support better clinical practices. This evidence-based approach can also help inform policy decisions, improve eye care programs/services striving towards equitable access to eye health services, locally and potentially globally.

3 What does participation in this research involve?

Participation involves allowing researchers to access and collect data from eye test records for yourself/your child/someone who you are caring for, including test results and clinical outcomes, and to approach you for other relevant research studies approved by a human research ethics committee.

Because ACO Eye Health delivers eye tests for up to 80,000 Victorians every year, it is not practical to seek individual consent from every person who has an eye test to be included in the database. Like other large scale health data collection projects taking place across Australia, it is not necessary to seek individual consent provided it is not possible to identify an individual from the data collected.

You will not need to sign a consent form as the opt-out process assumes consent unless you choose to withdraw.

There are no costs associated with participating in this research project, nor will you be paid.

The research is monitored to ensure ethical and scientific standards are maintained, and only approved researchers will access relevant parts of your records.

4 What do I have to do?

Participation simply involves allowing researchers to use data from your routine eye examination. There are no additional tests, visits, or requirements beyond your normal appointments at the ACO. The research requires no extra time or effort beyond your normal appointment(s), and your data will be used for research purposes only.

To participate in this research, you don't need to make any changes to your lifestyle, medications, or diet. You can continue your usual activities, including playing sports and donating blood.

5 Other relevant information about the research project

All patients receiving eye care from the ACO, unless they choose to opt-out, will contribute to this research. There are no predefined groups. Data from routine eye exams will be collected from all patients across all ACO sites and outreach services. This ensures a comprehensive dataset representing a wide range of eye health conditions.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether not to take part or withdraw, will not affect your routine treatment, your relationship with those treating you at the ACO.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits may help guide future improvements in clinical outcomes by providing evidence to improve care delivery, support better clinical practices and inform policy changes.

8 What are the possible risks and disadvantages of taking part?

We will do our best to protect your routinely collected data during collection, storage and when they are shared in presentations, publications, reports or relevant stakeholder meetings. The ways we will minimise the risk are described below. However, there remains a possibility that someone could identify you and therefore privacy breached or processes unintentionally are not followed. We cannot reduce the risk to absolute zero.

9 What if I withdraw from this research project?

You are free to withdraw the eye test records to be used for research purposes, for yourself/your child/someone you care for. You may also withdraw to being contacted about future ACO research projects. You don't need to give a reason, and opting out will not change the eye care we deliver to you, your child or someone you care for.

To opt-out, simply notify ACO Clinic staff, the researchers or complete an opt-out form for yourself (or your child under 18 years of age, or someone you care for) and hand it to the clinic receptionist. This will then be recorded in your clinical records.

10 What happens when the research project ends?

When new relevant information is published, a summary of the results will be available on the ACO website and be available in the Clinic waiting areas.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

For this research, the routinely collected information from your eye test record is stripped of 'identifiable data', which is information that could identify you (or your child, or someone you care for) as an individual, like name, home address, or having a rare medical condition. This de-identified data will then be stored in the ACO's cloud-based storage system where it is password-protected and only available to the researchers. The digital research data will be stored for at least 5 years from the date of final publication, of which, it will then be destroyed.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the organisations relevant to this Participant Information Sheet, ACO and NVRI, or as required by law. Without action, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Most data will be presented as a collective group, however, if individual information (for example a photo of your eye) is presented, a pseudonym (made up name) will be provided instead of your real name.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

12 Complaints

It is unlikely you/your child/someone you care for will suffer any injuries or complications as a result of this research. If you have any complaints regarding your treatment at the ACO, please follow up directly with the ACO Clinic staff for assistance.

13 Who is organising and funding the research?

This research project is being conducted by the ACO and NVRI, using funding from the NVRI Trusts and Victorian Lions Foundation. Each of these are public benevolent, not-for-profit organisations who exist to benefit Victorian and wider communities.

If knowledge acquired through this research leads to discoveries that are of commercial value to the ACO, the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). Any revenue will be used for future research or other services aiming to benefit Victorian and wider communities.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The University of Melbourne.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023). This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information:

Research contact person

Name	Dr Tim Fricke
Position	Director of Research and Education
Telephone	03 9349 7400
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Clinical contact person

Name	Dr Josephine Li
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Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Human Research Ethics Committee of the University of Melbourne
HREC Executive Officer	Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010
Telephone	+61 3 8344 1376
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