Survey of potential participant perspective on ocular gene therapy in Australia

SECTION 1 YOUR COPY
Survey of potential participant perspective on ocular gene therapy in Australia

Introduction

The Centre for Eye Research Australia invites people living with inherited retinal diseases and their parents/guardians to share their views and opinions about new potential gene therapy treatments.

For thousands of Australians living with inherited retinal diseases so far there has been little that could be done to slow down progressive vision loss.

But there are exciting new possibilities on the horizon. In fact, the first gene therapy treatment for inherited retinal diseases are expected to be available within Australia in the next few months.

To help researchers understand how we can support people in navigating information about potential gene therapy treatments, we’d like to invite anyone who is living with an inherited retinal disease to take this questionnaire.

We are also seeking input of parents and guardians of children with inherited retinal disease.

By answering these questions, you will share with us your lived experience and your views and opinions about upcoming gene therapy treatments.

This information will not only help us understand your unique perspective, but will also help us ensure people are well informed about emerging gene therapy treatments.

To take this survey, please first read the Plain English Statement for Participants that follows:

You can keep this first booklet for your own records.
Survey of potential participant perspective on ocular gene therapy in Australia

Plain English Statement for Participants

Plain Language Statement for Participants
Project title: Survey of potential participant perspective on ocular gene therapy in Australia

Researchers:
A/Prof Heather Mack (principal investigator), Dr Lauren Ayton (responsible investigator), A/Prof Fred Chen, A/Prof John Grigg, Dr Thomas Edwards, Ms Fleur O’Hare, Ms Ceecee Zhang, Prof Keith Martin

Contact: IRD@groups.unimelb.edu.au

Why is the study being conducted?
We are conducting research into the knowledge of Australian people with inherited retinal disease (IRD) regarding gene therapy for their condition. There has been a lot of progress in the field, and an Australian government approved treatment will be released shortly (Luxturna™ treatment for RPE65 retinal dystrophy), and we are interested to understand your knowledge of these treatments.

What do I need to do?
As part of this study, you are invited to complete a survey. The questions ask about how your condition has impacted your lifestyle, what you know about clinical trials in general, and what you know about government approved gene therapy to be released shortly. The survey will take about one hour to complete.

At the end of the survey you will be asked if you want to be contacted for more information on IRD genetic testing, if you want to receive a lay person summary of the report findings and if you are happy for your de-identified responses to be stored for possible future closely related studies.

Your participation is entirely voluntary.

How will be participants be selected?
Participants will be people with inherited retinal disease (IRD) who are Australian residents and English speaking, and/or their parents/guardians.

We will include people from a range of backgrounds and experiences, and therefore you will be asked to provide details of your condition and any previous experience with treatments.

Your personal details will remain confidential at all times.
Survey of potential participant perspective on ocular gene therapy in Australia

Plain English Statement for Participants

At the end of the survey, you have the option to list your contact details so that we can contact you with further information, or for future studies. This contact information will not be shared with others and will only be accessible to the named investigators in the study.

How will this research be used to benefit the community?
The survey results will assist us understanding how people with inherited retinal disease view gene treatment of their condition, and may inform future clinical trials of treatment for inherited retinal disease.

What are the risks?
There are no anticipated risks in taking part. The questions asked will not contain sensitive information. However, if you experience any distress from participation, please contact your GP for professional guidance and advice. Our research team are also available to discuss any concerns that you may have, or feelings of distress from the questions – you can contact us via email IRD@groups.unimelb.edu.au.

Additional resources are available if you do experience distress, including:

- Lifeline 24 hour counselling 131114
- Lifeline Victoria Suicide 24 Hour helpline 1300 651 251
- Beyond Blue 1300 224 636
- Veterans Counselling Service 1800 011 046
- Royal Victorian Eye and Ear Hospital consumer liaison officer 03 9929 8666
- Sydney Eye Hospital patient liaison officer 02 9382 7111
- Retina Australia 1800 999 870
- Vision Australia 1300 847 466
Survey of potential participant perspective on ocular gene therapy in Australia

Plain English Statement for Participants

Am I free to withdraw?
Participation in this study is completely voluntary and you may withdraw at any time with no risk of negative consequences.
If you choose to not participate this will not affect your relationship with your ophthalmologist or patient support group, or access to any future treatment that may become available for you. If you choose to withdraw your participation in this study, we will not be able to remove your data (as it is de-identified).
However, if you have provided us with your personal details for further contact, we can remove that from our database.
You may be in a doctor-patient relationship with one or more of the researchers listed in this study. It is important that you are aware that this potential conflict of interest will be managed in the following ways:

1. Your doctor will not know the answers you provide to the survey.
2. Your doctor will not know whether or not you participate in the study.
3. Your participation, or decision not to participate, will not affect your relationship with your doctor, or your medical care.

How do I express consent?
You will sign the consent form that appears at the end of this booklet, which you will keep for your records.
At the start of the survey questions you will sign another consent form that is returned to the researchers with your responses to the survey.
Survey of potential participant perspective on ocular gene therapy in Australia

Plain English Statement for Participants

How will my confidentiality be protected?
Your contribution to the survey will be collected and data will be stored in a secured location at the Centre for Eye Research Australia for a period of fifteen years. All participants’ personal details will be confidential. All data will be anonymized (including names, locations and conditions) and you will not be identifiable within any publications made as a result of this study.

If you provide us with your contact details at the end of the survey, we will contact you for the reasons you have selected (receiving a summary of the study findings and/or finding out more information about genetic testing in IRD).

Will participating cost me anything?
No, participating in the study is completely free of charge.

Will I be reimbursed for my time?
No, you are participating voluntarily to improve researchers’ understanding of your knowledge regarding treatments for your condition. You will not receive any payments, incentives or reimbursements for your participation.

Dissemination of results
We intend to publish the results of this study. If you indicate at the end of the survey, and leave your email address, you will receive a de-identified copy of the aggregated results at the completion of the study (anticipated in 2022).

These reports of de-identified aggregated results will also be provided to patient support groups which have assisted in participant recruitment. Study results will be disseminated to the scientific community through scientific publications in peer-reviewed journals and presentations in relevant national and international conferences.
Survey of potential participant perspective on ocular gene therapy in Australia

Plain English Statement for Participants

Ethics approval
This research project has been approved by the Human Research Ethics Committee of The University of Melbourne (project ID 2057534.2). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: humanethics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

Research funding
This project is being funded by the investigators, with no financial involvement from pharmaceutical companies. The project is supported in part by a 2021 research grant from Retina Australia to Drs Mack, Grigg, Chen and Ayton.

What happens now?
If you would like to participate, you can complete the attached hard copy paper form.
Or you can chose to complete the survey online at www.cera.org.au/ird-survey
If you would prefer a hard copy form, and have not already received one, please contact:

Ms Ceecee Zhang
Study Co-ordinator
Email: IRD@groups.unimelb.edu.au
Ph: (03) 9929 8621
Please also contact the researchers on the above details if you have low vision and want to dictate your answers to a researcher who will enter the data on your behalf.

What if I want more information about the study?
For additional information about the project, please email: IRD@groups.unimelb.edu.au.
Survey of potential participant perspective on ocular gene therapy in Australia

Consent form – Version 2 - 5 January 2021

I consent to participate in the research study “Survey of potential participant perspective on ocular gene therapy in Australia” and confirm that I have read the plain language statement and understood the following information.

In particular, I have noted that:

☐ Participation in this research is entirely voluntary;

☐ I am free to withdraw from this research at any time, without comment or penalty. If I withdraw I may request withdrawal of any unprocessed data previously supplied;

☐ Providing my contact details to the researchers is entirely voluntary;

☐ Any questions have been answered to my satisfaction and I understand that if I have any additional questions I can contact the research team;

☐ I have been informed that the confidentiality of the information I will provide will be safeguarded, my opinions will be treated as personal information, and my privacy respected;

☐ My de-identified data will be stored and may be utilized for future related research studies on the understanding that consent for further projects will be sought from me at that future time;

☐ I understand that I can contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: humanethicscomplaints@unimelb.edu.au.

Name: ________________________________

Sign: ________________________________

Date: ________________________________

Thank you for reading this information. This section is for you to keep for your own records.
Centre for Eye Research Australia
Royal Victorian Eye and Ear Hospital
Peter Howson Wing
Level 7, 32 Gisborne Street
East Melbourne 3002
VIC Australia