PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

Version: 4.0 – Dated 28th June 2022

Title	The Australian Eye and Ear Health Survey
Short Title	Australian Eye and Ear Health Survey
Protocol Number	TBC
Ethics Clearance No.	USYD HREC: 2020/818 AIATSIS: EO303-20211008
Project Sponsor	Australian Government, Department of Health
Principal Investigator	Professor Paul Mitchell
Associate Investigator(s)	Associate Professor Gerald Liew, Professor Bamini Gopinath, Professor Lisa Keay, Associate Professor Gian Luca Di Tanna, Ms Colina Waddell, Dr Tim Fricke
Primary Organisation	The Westmead Institute for Medical Research
Duration:	Feb 2022 – June 2024
Site Location	La Perouse – Chifley – Malabar

This Participant Information and Consent Form is **8** pages long.

Please make sure you have all the pages.

Introduction

You are invited to take part in this research project, ***The Australian Eye and Ear Health Survey.*** The research project is aiming to **find out how common major eye diseases and hearing loss are in Australians living in urban, regional and remote areas.**

This Participant Information and Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or 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. You will receive the best possible care whether you take part or not.

If you decide to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project and to be contacted about any subsequent follow up projects;
- Consent to the tests and research that are described;
- Consent to the use of your personal and health information as described;

You will be given a copy of this Participant Information and Consent Form to keep.

Purpose and Background

The purpose of this project is to ***work out the leading eye diseases and conditions causing blindness, and hearing loss in Australia. The following are the objectives and significance of the study:***

Objectives

1. To find out how common vision impairment and blindness, and hearing loss is in in Indigenous Australians aged 40 years and over, and non-Indigenous Australians aged 50 years and over, by gender, age, and geographical area. We will also find out the causes of vision and hearing loss.

2. To find out if treatment is being accessed for eye diseases, including cataract, diabetic retinopathy, glaucoma, age-related macular degeneration and refractive error in both Indigenous and non-Indigenous Australian adults by:

   a) Determining the proportion of Australians with undiagnosed major eye diseases and uncorrected refractive error (need for glasses).

   b) Determining the proportion of Australians with known diabetes who adhere to the recommended retinal examination timeframes set by the National Health and Medical Research Council (NHMRC); once every two years for non-Indigenous Australians and once per year for Indigenous Australians.

   c) Determining an estimation of the coverage rate and quality of treatment outcomes for cataract surgery and the treatment of uncorrected refractive error in Australia

3. Determining the proportion of Australians with undiagnosed hearing loss.

This research is being led by: Professor Paul Mitchell, in association with Associate Professor Gerald Liew from the University of Sydney and Centre for Vision Research (Westmead Institute for Medical Research), Professor Lisa Keay from UNSW School of Optometry, Associate Professor Gian Luca Di Tanna from The George Institute for Global Health, Ms Colina Waddell and Dr Tim Fricke from the Brien Holden Foundation, and Professor Bamini Gopinath from Macquarie University.

This research has been funded by the Australian Government, Department of Health and Macquarie University.

Significance

The Australian Eye and Ear Health Survey will assist in eye and hearing health care in multiple ways, including:

1. helping to measure the progress and impact of eye and hearing health care services in Australia;
2. guiding the use of necessary resources in reducing the number of Australians with avoidable vision and hearing impairment;
3. assisting in developing effective, feasible and cost-effective eye and hearing health care services in Australia;
4. aiding in developing education, awareness and screening programs in communities, including regional and remote areas, for the prevention of eye disease and hearing loss.

A total of ***5000 Australians*** will participate in this project.

Why have I been invited to participate?

You have been invited to participate in this study because you are an Indigenous Australian over the aged 40 or over, or a Non-Indigenous Australian aged 50 years or over living in one of the 30 areas of Australia randomly selected to be included in the study. These age specifications were chosen based on existing knowledge on the age groups most commonly impacted by vision and hearing impairment in Australia. Participants must be cognitively and legally able to provide informed written consent and have reasonable English fluency and/or have a person to interpret for them.

What is Involved?

If you agree to participate in this survey, and you meet the inclusion criteria of the survey determined by age and residence, you will be invited to attend one of the survey testing sites (specified on Page 1) to complete a short questionnaire and undergo a series of eye tests. Testing will take approximately 1- 1.5 hours to complete. If you wish to participate in the hearing survey (approximately 30 minutes), you will have the option to schedule this on the same day as the eye survey or on a different day when you make your appointment. This assessment will be a one-off (no follow-up required) and will occur on a day of your choosing between the **29/06/22 – 15/07/22**.

General Questionnaire

The general questionnaire will ask about personal particulars, including age, gender and ethnicity. It will also include a thorough history of your general, eye and hearing health.

Please bring: (1) your glasses if you have a pair and (2) tablets, supplements, eye drops or other medications (or photos of the medication labels) you are currently taking, and a list of any medications regularly taken in the last 5 years.

General Tests

There will be some examinations that will be conducted, these include:

- Weight and height
- Blood pressure
- Random blood glucose (finger prick)

Eye Tests & Dilating Eye Drops

There will be a number of eye tests that will be conducted. There may be slight discomfort associated with some of these tests as outlined below in the *Possible Risk* section. It is very important that we have a clear view inside your eye to check it is healthy. To do this we will need to put some drops in each eye to dilate your pupil. These might sting a little but will go very quickly and not cause lasting discomfort. Your vision may remain blurry for approximately 2 hours, you should not drive until your vision returns to normal and/or organize for someone to drive you home. The tests include:

- Checking your eye pressure
- Testing both distance and near vision
- Further non-invasive eye tests will be completed:
    - How clear your vision is and if you could benefit from glasses
    - Photos and scans of the back of your eyes including blood vessels
    - A visual field test to check your peripheral (side) vision
    - The front of your eyes to gauge general health of your eyes and eye lids

Hearing Tests

- Checking the condition of your ears
- Testing your hearing
- Testing the condition of your middle ear and mobility of your eardrum

Take-home questionnaire

An optional take-home questionnaire is provided to all participants. This questionnaire is also available online and can be accessed by scanning the QR code. The purpose of this take-home questionnaire is to collect additional information about the impact and lifestyle risk factors of eye conditions. Included questions ask about vision function, environmental noise exposure, physical activity and diet. If you need help to complete this questionnaire please ask.

Insert QR code

Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this research, however if an eye condition or hearing loss is identified by the survey you will be provided with an appropriate referral recommendation to an eye care professional or audiologist.

Possible benefits may include better guidance on eye care interventions for the broader community determined by this survey's results. Also, the Government will be better informed on the allocation of necessary eye and hearing health care services in Australia.

There are no costs associated with participating in this research project, nor will you be paid. However, participants will receive a pair of sunglasses upon completion of the examination.

Possible Risks

While this research does not involve any treatment, test procedures may cause some side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study researcher. Your study researcher will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study researcher immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study researcher may need to stop your involvement with the study. Your study researcher will discuss the best way of managing any side effects with you and a doctor if necessary.

Possible risks, side effects and discomforts include:

With eye drops, you may experience a stinging sensation for several seconds. The eye drops may also cause light sensitivity and will blur your vision (when looking at objects up close) for several hours. In rare situations (studies estimate it at 1 in 10000 people), the use of these drops can trigger a sharp increase in pressure in the eye causing pain and a red eye. If such an event occurs, please call the number listed below or seek eye care specialist services will be required immediately so that this can be treated. We do not advise you to drive if your vision is blurred and other arrangements

for transport should be put in place. We also advise you to bring sunglasses to the examination for comfort in daylight.

To avoid any physical discomfort with seating positions during eye and/or ear testing, we will ensure that you are comfortable at all times, however if you feel any discomfort at all during the testing please inform one of the examiners. Also, you will be offered frequent breaks to ensure optimal comfort during the entire course of the testing.

With some of the eye tests, particularly the camera used to take photos of the back of the eye, discomfort may be experienced with the flash used with the camera. This flash is the same as what you would experience using a regular camera. You will be given regular breaks to minimise any eye discomfort from these types of tests, but please do not hesitate to inform the examiner if longer breaks are required.

Participants can suspend or even end their participation at any time in the project if distress occurs.

There may be additional unforeseen or unknown risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that you get. You may also learn that you have an eye or ear condition that you were not previously aware of which may cause you some distress or anxiety. If you experience these feelings, please contact one of the support services listed on the last page of this form or speak to a member of the project team.

Other Treatments Whilst on Study

While you are participating in this research project, you will not need to stop any of your current treatment(s).

Alternatives to Participation

There is no standard procedure or treatment that is being withheld as a result of your participation in this study. You do not have to take part in this research project to receive treatment for any health condition you may have.

Participation is Voluntary

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. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the University of Sydney, The University of NSW, The George Institute for Global Health, Brien Holden Foundation or Macquarie University.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team as soon as possible via the contact details listed on page 8, or, if you decide to withdraw during the examination, please inform any available team member before leaving. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly. Please be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want them to do this, please tell them before you join the research project.

Results of Project

Participants will be informed via their preferred form of contact of the results when the research project is complete, and the data is published. General practitioners, eye specialists, audiologists and any other practitioners will also be informed about your results if you consent for this to happen. Also, media release, progress reports and associated newsletters will be accessible to all participants online.

Our study findings will be presented to the World Health Organisation (WHO), alongside the data from other countries who we actively work with to eliminate the burden of avoidable blindness worldwide. The current survey will provide useful information for policy planning and better direct the allocation of funds. De-identified data may also be published in scientific journals or other public forums. Authors of publications will be one or more members of the research team included the investigators listed in this document.

Privacy, Confidentiality and Disclosure of Information

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. **Any information obtained in connection with this research project that can identify you will remain confidential.** Your information can only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. Data will be stored for 5 years after study completion. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information. Culturally restricted information will not be collected.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored on a secured database or in a locked storage facility at the Westmead Institute for Medical Research. It will be disclosed only with your permission, as or required by law. Identifiable data will only be accessible by select members of the research team.

Injury

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. Support services available, should you need them at any time, are listed at the end of this document.

Who is organising and funding the research?

This research project is being conducted by ***Professor Paul Mitchell from the University of Sydney and Centre for Vision Research (Westmead Institute for Medical Research). The Australian Government Department of Health and Macquarie University have funded the project***.

There are no financial benefits that might arise from the conduct of the research. *The Westmead Institute for Medical Research* will receive a payment from *the Department of Health* for undertaking this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Ethical Guidelines

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 Sydney and AIATSIS Research Ethics Committee

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Who can I Contact?

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the **study coordinator on 0408 910 966** or any of the following people:

Name:	Professor Paul Mitchell
Position:	Principal Investigator
Telephone:	+61 (2) 9893 9076
Email:	paul.mitchell@sydney.edu.au
Name:	Professor Bamini Gopinath
Position:	Co-Investigator (Hearing)
Telephone:	+61 (2) 9850 8962
Email:	bamini.gopinath@mq.edu.au

For complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Organisation	The University of Sydney
Position:	Human Research Ethics Committee (HREC) Secretary
Telephone:	+61 2 9036 9161
Organisation	AH&MRC Ethics Committee
Position:	The Chairperson
Email:	ethics@ahmrc.org.au

You will need to tell the Secretary the name of one of the researchers listed above.

Reviewing Human Research Ethics Committee (HREC):

The reviewing HREC approving this research and contact details of the Executive Officer are:

Reviewing HREC name:	The University of Sydney
Position:	HREC Secretary
Telephone:	+61 2 9036 9161
Email:	human.ethics@sydney.edu.au
Reviewing HREC name:	AIATSIS Research Ethics Committee
Position:	Ethics Secretariat
Telephone:	(02) 6246 1681
Email:	ethics@aiatsis.gov.au

Support Services:

Support/Social Worker Services:

Well Mob

Social, emotional and cultural wellbeing online resources for Aboriginal and Torres Strait Islander People: https://wellmob.org.au/

Disability Gateway

National support service for all Australians with disability. Provides information on support services available: www.disabilitygateway.gov.au

Carer Gateway

National support service for those caring for a loved one with disability: www.carergateway.gov.au

Access to social worker via Centrelink (call and ask to speak to a social worker):

Older Australians line: 132 300

Indigenous Australians line: 1800 136 380

Other Services include:

Macular Disease Foundation Australia **-** 1800 111 709

Offers both Peer to Peer phone support and community support groups. The Peer-to-Peer program will give you the opportunity to speak to and share experiences with one of our volunteers. They either have been living with vision loss themselves or have a close friend or family member with macular disease. The Peer to Peer program is not a counselling service.

Vision Australia - 1300 84 74 66. Leading national provider of vision loss support and services and work with people of all ages and stages of life.

Beyond Blue: 1300 22 4636 open 24/7

Lifeline: 131 114

Stride Mental Health: https://stride.com.au

Yarn Safe: https://headspace.org.au/yarn-safe/ or https://headspace.org.au/headspace-centres/

Yarn Safe has information for young people who identify as Aboriginal and/or Torres Strait Islander.