Eye & Ear Hospital
caring in every sense

ROYAL VICTORIAN EYE & EAR HOSPITAL

PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

The University of Melbourne

Title	Optimisation of Hearing Aids for Children and Adults
Short Title	Optimisation of Hearing Aids
Protocol Number	
Project Sponsor	*The University of Melbourne*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Gary Rance*
Location	The University of Melbourne, School of Audiology

1. Introduction

You are invited to take part in this research project, "optimisation of hearing aids for children and adults". This is because you either have a hearing loss of appropriate degree or are a suitable control participant. The research project is aiming to investigate the capacity of a range of commercial hearing aids and free-field (loudspeaker) amplification systems to improve speech understanding, general communication and listener comfort in hearing impaired individuals. 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;
- 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.

2. Purpose and Background

Modern hearing devices can manipulate the loudness and frequency content of sounds to make them audible (detectable) to people with hearing loss. Manipulating complex signals (such as speech) can, however, affect how clear and comfortable the sounds are to listen to. The purpose of this project is to investigate the capacity of a range of commercial hearing aids and free-field (loudspeaker) amplification systems to improve speech understanding, general communication and listener comfort. In so doing, we will optimise the function of these devices to produce the best possible clinical outcomes in children and adults with hearing loss.

Previous experience has shown that commercial hearing aids have been produced with a number of fitting options, but that not all of these have been thoroughly tested in listeners of different ages or

with hearing characteristics (eg. degree/type of hearing loss). We will explore these hearing-aid fitting options in different subject populations.

A total of ***350*** people will participate in this project.

This is a new study that does not follow-on directly from other research. The project has been initiated by Associate Professor Gary Rance

3. Procedures

Participation in this project will typically involve a single test session lasting 1-1½ hours. (In some studies where changes made to the hearing aid settings require an adjustment period, a follow-up session may be required. The test battery comprises: a hearing (sound detection) test, basic auditory processing testing (sound localisation, pitch discrimination, signal identification), speech perception assessment and a brief hearing/communication survey. Testing will be repeated with different hearing-aid settings and the results compared.

By signing this consent form you also give us permission to access the results of previously conducted hearing tests.

4. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this research. We do, however, expect to gain insights that will allow your hearing aids to be optimised (if you are an aid user). Specific advice regarding hearing-health, everyday listening strategies will also be offered as appropriate.

5. Possible Risks

The test procedures in this study are based on standard clinical techniques. There are no foreseeable risks. Aided testing will either use your own hearing device(s) or loaner device(s) that have not been modified beyond the standard user settings. Sound presentation levels will be strictly controlled to minimise the risk of unpleasant sound levels.

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

6. New Information Arising During the Project

Sometimes during the course of the research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

7. Other Treatments Whilst on Study

While you are participating in this research project, you may not be able to take some or all of the medications or treatments that you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

8. Alternatives to Participation

You do not have to take part in this research project and can continue to receive routine management from your referring audiology clinic.

9. 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 Royal Victorian Eye & Ear Hospital or your referring audiology clinic.

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 before you withdraw. 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 and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

10. Termination of the Study

This research project may be stopped unexpectedly for a variety of reasons. These may include consistently poor outcomes in the early trial phases or unresolvable technical issues.

11. Results of Project

Public dissemination of the overall findings will be in the form of refereed journal articles. These publications will contain no identifying features and will be made available to all participants upon request to A/Prof Gary Rance.

A lay summary (also with no identifying features) will be available to participants at the end of the study. This document will be available on-request from the Principal Investigator (grance@unimelb.edu.au).

12. 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. Records relating to each subject will be kept until the completion of data collection (5 years) at which point all information will be de-identified. Each subject will be allocated a subject number, and all identifying information will be shredded. All computer files will be stored on password secured systems accessible only to the Principle Investigator. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project

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) by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, [University of Melbourne], or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study 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.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. 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.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, as or required by law.

13. 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. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

14. Who is organising and funding the research?

This research project is being conducted by Associate Professor Gary Rance.

The University of Melbourne may benefit financially from this research project if, for example, the project assists a hearing aid company to obtain approval for a new device. You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value**.** In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the University of Melbourne the study doctors 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).

15. Additional costs and reimbursement

There are no costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

16. 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 Royal Victorian Eye & Ear Hospital.

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.

17. 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 principal study doctor on (03) 9035 5342.

Clinical contact person

Name	*Gary Rance*
Position	*Principal Investigator*
Telephone	*BH: 9035 5342 AH: 9585 5079*
Email	grance@unimelb.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

Position: HREC Secretary

Telephone: (03) 9929 8525

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

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

Reviewing HREC name: Royal Victorian Eye & Ear Hospital

Position: HREC Secretary

Telephone: (03) 9929 8525

Email: ethics@eyeandear.org.au

CONSENT FORM - Adult providing own consent

Eye & Ear Hospital
caring in every sense

The University of Melbourne

Title	Optimisation of hearing aids for children and adults
Short Title	Optimisation of hearing aids
Protocol Number	
Project Sponsor	*The University of Melbourne*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Gary Rance*
Location	*The University of Melbourne, School of Audiology*

Declaration by Participant

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……

Signature Date

Witness (where required – see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9)

Name of Witness* to Participant's Signature (printed) ……

Signature Date

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by study doctor/senior researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

CONSENT FORM FOR MINORS

(To be used by parents/court appointed guardians of minors)

Eye & Ear Hospital
caring in every sense

The University of Melbourne

Title	Optimisation of hearing aids for children and adults
Short Title	Optimisation of hearing aids
Protocol Number	
Project Sponsor	*The University of Melbourne*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Gary Rance*
Location	*The University of Melbourne, School of Audiology*

Declaration by Parent/Guardian

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for the child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Royal Victorian Eye & Ear Hospital concerning the child's disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……

Name of Person giving Consent (printed) ……

Relationship to Participant: ……

Signature Date

Witness (where required – see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9)

Name of Witness* to Parent/Court Appointed Guardian's Signature (printed) ……

Signature Date

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant's parent/guardian has understood that explanation.

Researcher's Name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

CONSENT FORM - Person Responsible

Eye & Ear Hospital
caring in every sense

The University of Melbourne

Title	Optimisation of hearing aids for children and adults
Short Title	Optimisation of hearing aids
Protocol Number	
Project Sponsor	*The University of Melbourne*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Gary Rance*
Location	*The University of Melbourne, School of Audiology*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……

Name of Person Responsible giving consent (printed) …….

Relationship of Person Responsible to participant: …….
(as defined by the Guardianship and Administration Act 1986)

Signature Date

Witness

Name of Witness to Person Responsible's Signature (printed) ……

Signature Date

Declaration by study doctor/senior researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

Researcher's Name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

FORM FOR WITHDRAWAL OF PARTICIPATION

It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant's decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.

Eye & Ear Hospital
caring in every sense

The University of Melbourne

Title	Optimisation of hearing aids for children and adults
Short Title	Optimisation of hearing aids
Protocol Number	
Project Sponsor	*The University of Melbourne*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Gary Rance*
Location	*The University of Melbourne, School of Audiology*

Declaration by Participant

I wish to WITHDRAW from participation in the above research project and understand that such withdrawal WILL NOT affect my routine treatment, my relationship with those treating me or my relationship with the Royal Victorian Eye & Ear Hospital.

Participant's Name (printed) ……..

Signature Date

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Research will need to provide a description of the circumstances below.

Declaration by study doctor/senior researcher*: I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Researcher's Name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

Eye & Ear Hospital
caring in every sense

ROYAL VICTORIAN EYE & EAR HOSPITAL
EXPERIMENTAL PARTICIPANT'S STATEMENT OF RIGHTS

The Royal Victorian Eye and Ear Hospital considers it important that you know:

Any patient who is asked to participate in a research study involving medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed and any drugs used in the medical experiment.

3. Be given a description of discomforts and risks reasonably expected from the experiment, if applicable.

4. Be given an explanation of any benefits to the participant reasonably to be expected from the experiment, if applicable.

5. Be advised of appropriate, alternative procedures, drugs, or devices that might be advantageous to the participant, and their relative risks and benefits.

6. Be informed of the avenue of medical treatment, if any, available to the participant after the experiment if complications should arise.

7. Be given an opportunity to ask questions concerning the experiment or the procedures involved.

8. Know that consent to participate in the medical experiment may be withdrawn at any time, and that the participant may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence.