Eye & Ear Hospital
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ROYAL VICTORIAN EYE & EAR HOSPITAL

PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

TEMPLATE FOR NON-CLINICAL DRUG RESEARCH PROJECTS

University of Melbourne

Participant Information and Consent Form
Version 4: Dated 12 November 2012

Site: Royal Victorian Eye and Ear Hospital

Full Project Title: Post-mortem Study of Temporal bone and Brain Histology in Patients with Hearing and/or Balance Disorders

Principal Researcher: Prof Stephen O'Leary

Associate Researcher(s): Dr David Szmulewicz

This Participant Information and Consent Form is10 pages long. Please make sure you have all the pages.

1. Introduction

You are invited to take part in this research project because you have a hearing and/or balance condition that may be better understood by 'after death' (post-mortem) examination of the inner ear (temporal bone structures) and/or brain. This research project is aiming to make a detailed 'microscopic' (histological) analysis of the human inner ear and/or brain in order to improve the cochlear implant and better understand diseases of hearing and balance.

This Participant Information and Consent Form contains information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project to help you decide whether or not to take part in the research.

Please read this information carefully. Feel free to ask questions about any information in the document that you don't understand or want to know more about. You may also wish to discuss the project with a relative, friend or healthcare worker. Feel free to do this.

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.

Once you understand what the project is about and if you decide to take part in it, 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 participate in the research processes 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

The purpose of this project is to better understand diseases that effect hearing and/or balance, including the effect of cochlear implantation. The most valuable information available would come from an 'after death' examination of the inner ear and brain of patients with hearing and/or balance disorders. It is envisaged that your participation in this project would help us further the medical

understanding of hearing and balance disorders (including the effects of cochlear implantation) in an effort to improve medical treatment.

We also ask that you consider allowing us to collect a blood sample or cheek swab, so that we may store your DNA and use this to help understand whether there is a genetic component to your hearing and/or balance disorder. The DNA would be stored at the Murdoch Children's Research Institute which has the specialized secure facilities to process and store DNA.

Previous experience has shown that much of what we know in humans about diseases of the ear and brain has come from this type of investigation, where people with hearing and/or balance disorders or those with cochlear implants have generously donated their ears and brains for scientific examination.

Any person with an ear and/or balance disease, or a cochlear implant, is welcome to participate in this project.

This research has been initiated by the investigator, Professor Stephen O'Leary**.**

This research has been partly funded by the Garnett Passe and Rodney Williams Memorial Foundation.

3. Procedures, and What is Involved

Participation in this project will involve performing an analysis of the ear bone(s) and when also donated, the brainstem. The outcomes of this investigation will be related back to the medical history of your hearing or balance disorder, and where applicable the performance of your cochlear implant.

4. Possible Benefits

There may be benefits to future generations through what is learnt about inner ear and brain disease from your donation.

5. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged 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 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.

Before you make your decision, a member of the research team will be available to answer 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 inform you if there are any health risks or special requirements linked to withdrawing.

6. Privacy, Confidentiality and Disclosure of Information

Any information obtained in connection with this project hat can identify you will remain confidential and securely stored.

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 access the information collected and stored by the researchers about you. You also

have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in this document if you would like to access your information.

Samples of your blood and/or tissue obtained for the purpose of this research project will be held by the University of Melbourne, Department of Otolaryngology, and in the case of DNA (extracted from a cheek swab or blood sample), by the Murdoch Children's Research Institute. Your tissue will not be sold. It is envisaged that any tissue you donate (including DNA) will be securely stored for an unspecified period of time to allow for future research that is in keeping with this research project.

7. Reimbursement for your costs

You will not be paid for your participation in this research.

7A. Results of Project

All participants will be informed of the results when the research project is completed by written letter which will be sent by regular post.

8. Ethical Guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee 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) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

9. Who can I Contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:
Professor Stephen O'Leary (03) 99298366

Dr David Szmulewicz (03) 99298666

Email: temporalbonebank@eyeandear.org.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

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Consent Form : Version 4 Dated: 12th November 2012
Full Project Title: Post-mortem Study of Temporal bone and Brain Histology in Patients with Hearing and/or Balance Disorders

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

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 project according to the conditions in this document.

I agree to the donation of my:

☐ Inner ears (temporal bones)

☐ Brain

☐ Supply a DNA sample (via blood sample or a check swab)

I will be given a copy of the Participant Information and Consent Form to keep

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed) …….

Signature Date

Witness (Required when participant cannot read this document for him/herself except where an interpreter is used.)

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

Signature Date

If the project is likely to involve the use of interpreters include:

Interpreter (Required when this document is read to the participant in a language other than English.)

Name of Interpreter (printed) …….

Signature Date

Declaration by 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)

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Consent Form for Minors
Version 4 Dated: 12th November 2012
Full Project Title: Post-mortem Study of Temporal bone and Brain Histology in Patients with Hearing and/or Balance Disorders

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I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

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

I give my permission for _____to participate in this project according to the conditions in this document.

I agree to the donation of _____'s:

☐ Inner ears (temporal bones)

☐ Brain

☐ Supply a DNA sample (via blood sample or a check swab)

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

The researcher has agreed not to reveal the participant's identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed) ……

Name of Person giving Consent (printed) ……

Relationship to Participant: ……

Signature Date

Name of Witness to Parent/Court Appointed Guardian Signature (printed) …….

Signature Date

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 FOR ADULTS WHO LACK CAPACITY TO CONSENT

(To be used for participants who cannot consent for themselves, as defined by the Guardianship and Administration Act 1986)

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VERSION 4 DATED: 12TH NOVEMBER 2012

FULL PROJECT TITLE: POST-MORTEM STUDY OF TEMPORAL BONE AND BRAIN HISTOLOGY IN PATIENTS WITH HEARING AND/OR BALANCE DISORDERS

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I am the Person Responsible for _____ I acknowledge that the researchers would like to enrol _____ in the research project named above, according to the conditions in this document.

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

I believe that the carrying out of the procedure is not contrary to the best interests of _____.

I agree to the donation of _____'s:

☐ Inner ears (temporal bones)

☐ Brain

☐ Supply a DNA sample (via blood sample or a check swab)

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal _____'s identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed) …….

Name of Person giving consent (printed) …….

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

Signature Date

Witness to Signature (printed) …….

Signature Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the person named above as the Third Party 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 TO PARTICIPATE IN RESEARCH

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INTERPRETER: If an interpreter is used, the following addition is necessary -

I _____

(name of interpreter) of

_____ certify as follows: I am qualified to translate speech and writing from the English language into the _____ language and vice versa. I read the Participant Information Sheet to the participant in the _____ language and he/she appeared to understand it. I was present when the researcher explained the general purposes, methods, demands and possible risks and inconveniences of participating in the study to the participant and I translated all that was said by the researcher and by the participant from the English language into the _____ language and vice versa. I was present when the independent witness spoke to the participant and I translated all that was said by the independent witness and by the participant from the English language into the _____ language and vice versa.

Signature of Interpreter _____

Date _____

REVOCATION OF CONSENT FORM

(To be used for participants who wish to withdraw from the project.)

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Revocation of Consent Form

Version 4 Dated: 12th November 2012
Full Project Title: Post-mortem Study of Temporal bone and Brain Histology in Patients with Hearing and/or Balance Disorders

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with **the Royal Victorian Eye & Ear Hospital.**

Participant's Name (printed) ……

Signature Date

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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.