



PARENT/GUARDIAN INFORMATION STATEMENT AND CONSENT FORM

HREC Project Number: 27148

Research Project Title: The SCOUT study: Statewide Comparison of Outcomes of Hearing Loss

Thank you for taking the time to read this Information Statement. This Information Statement and Consent Form is 4 pages long. Please make sure you have all the pages.

For people who speak languages other than English: If you would also like information about the research and Consent Form in your language, please ask the person explaining this project to you.

You are invited to participate in a research project that is explained below.

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you to decide whether or not you would like your child to take part in the research.

Please read this Information Statement carefully. You can ask us questions about anything in it. You may want to talk about the project with your family, friends or health care worker.

Participation in this research project is voluntary. If you don't want your child to take part, you don't have to. You can withdraw your child from the project at any time without explanation and this will not affect their access to the best available treatment options and care from the Royal Children's Hospital.

Once you have understood what the project is about, if you would like your child to take part please sign the consent form at the end of this information statement. You will be given a copy of this information and consent form to keep.

1. What is the research about?

Now that newborn hearing checks are available, hearing loss is often picked up soon after birth. However, no one really knows how effective newborn hearing screening is. It's important to find out. Hearing screening programs are very expensive, so governments need to know that they are worthwhile.

Between March 2003 and February 2005, all New South Wales babies were offered a newborn hearing screen as part of the Statewide Infant Screening- Hearing (SWISH) program. In Victoria, only babies in the neonatal intensive care unit were offered a newborn hearing screen. All other babies were checked for risk factors for hearing loss via the Victorian Infant Hearing Screening Program (VIHSP). In March 2005, Victoria began its own newborn hearing screening program. Therefore, this two-year period is the only window of opportunity to compare outcomes from the two programs.

SCOUT aims to compare the language, behaviour and general health status of children with congenital bilateral hearing loss born in NSW and Victoria between 2003 and 2005. We are asking the following questions:

1. How does universal newborn hearing screening program compare with a traditional risk factor identification program in relation to children's status at five years of age?
2. Which program is most beneficial to children?
3. How cost-effective is universal newborn hearing screening?

2. Who are the researchers?

- Associate Professor Melissa Wake: Paediatrician and Director (Research and Public Health) at the Centre for Community Child Health, Royal Children's Hospital, Murdoch Childrens Research Institute & The University of Melbourne.
- Dr Teresa Ching: Audiologist and Senior Research Scientist, National Acoustic Laboratories (NAL)
- Dr Zeffie Poulakis: Psychologist and Director of the Victorian Infant Hearing Screening Program, Royal Children's Hospital, Murdoch Childrens Research Institute & The University of Melbourne
- Lisa Gold: Health Economist and Senior Research Fellow, School of Health and Social Development, Deakin University
- Professor Field Rickards: Dean, Melbourne Graduate School of Education, The University of Melbourne
- Professor Sheena Reilly: Director of Speech Pathology at the Royal Children's Hospital, and Director of the Healthy Development Theme at the Murdoch Childrens Research Institute & The University of Melbourne.

3. Why is my child being asked to be in this research project?

We are inviting your child to join SCOUT because he/she:

- has a hearing loss in both ears, which was probably present from birth
- was fitted with hearing aids or a cochlear implant by the age of 4 years
- was born between March 2003 and February 2005 in New South Wales or Victoria.

We are inviting all children who fit this description to join SCOUT.

We are interested in comparing the costs and the outcomes for the children born in these two states, even if they didn't get (or act on) a hearing or risk factor screen.

4. What does my child need to do to be in this research project?

We are aware that you are also taking part in the 'LOCHI' study on outcomes of children with hearing loss being conducted by the National Acoustic Laboratories (NAL). The study that we are now inviting you to participate in compliments the aims of the LOCHI study.

Given that you have already contributed a lot of valuable information to the LOCHI study, we are asking for your permission for us to receive a copy of your child's study information from NAL so that we don't double up on the work and time that you and your child have already contributed. The following list is additional information that we would like to collect from you and your child for this study:

- Two brief questionnaires which should take about 30 minutes of your time. They ask about your child's general health, what services you use for your child's hearing loss, and about you and your partner (if applicable).

We will also arrange a time for a researcher to visit you and your child at home, or somewhere convenient to you. The visit will take about 45 minutes. At this visit, the researcher will:

- go through a simple questionnaire with your child about his/her own well-being
- give you the second of the two questionnaires to fill out while your child is busy with the assessment and interview you briefly
- seek your written permission to access information about your child from the following services: NAL, Australian Hearing, the Cochlear Implant Clinic, Early Intervention Services and Medicare. The consent forms for this are different from the ones in the envelope with this Information Statement. A researcher will go through them with you, and answer any questions you have. You don't have to agree to this part of the study now.

5. What are my child's alternatives to taking part in this project?

You do not have to take part if you do not want to. Or you can decide to take part in the assessments and questionnaire, but not to give us access to your child's health services information.

If you decide to take part and later change your mind, you are free to withdraw at any stage without consequence. If you don't take part or you withdraw, it will not affect any standard care and treatment you or your child will receive from the Royal Children's Hospital.

6. What are the possible benefits for my child?

You and your child won't directly benefit from taking part in SCOUT. However, we will provide you with the option of a short report of your child's results if you would like one.

7. What are the benefits for other people in the future?

Babies born now are often diagnosed with a hearing impairment much earlier than was possible in the 1990s. This study will help answer important questions about the effectiveness of universal newborn hearing screening (UNHS) programs. If these programs are to continue, it's important to know that they are effective. Nowhere else in the world has had two complete programs running in parallel, like the NSW and Victorian programs described above. Therefore, this study will provide information needed not just for Australian children but for children around the world.

8. What are the possible risks, side-effects and/or discomforts?

We don't think your child will be at any risk because of the study. Some children do get tired during assessments. If this happens, we'll make another time to come back and complete it.

If you have any questions, please contact the research team. The phone number is at the end of this information statement.

9. What are the possible inconveniences?

You will need to spend about 30 minutes filling out the questionnaire. The home visit will take between 30 and 45 minutes.

10. What will be done to make sure my child's information is confidential?

Any information we collect from you will remain confidential. We will only use your information for this research project. Only the researchers involved with this project and the Royal Children's Hospital Ethics Committee can have access to this information. We can only disclose the information with your permission, except as required by law.

You have the right to look at, and ask correction of, your information in accordance with the Freedom of Information Act 1982 (Vic).

The information you give us will be de-identified. This means that we will remove your name and give your information a special code number. Only the research team will be able to break the code to match your name to your code number.

All information will be stored securely in a locked filing cabinet in the Centre for Community Child Health (CCCH) at the Murdoch Childrens Research Institute. Your information will also be stored on a password-protected computer database.

As required for all research projects conducted at the Royal Children's Hospital, if either you or your child are aged under 18 years old we will keep the information until both you and your child turn 25 years old. After this time, we will destroy the information by shredding documents and/or deleting computer files.

When we write or talk about the results of this project, we will only report information about the whole group of participants. This means that no one will be able to identify you (your child or your family).

11. Will we be informed of the results when the research project is finished?

We will mail you annual newsletters about the progress of the project and a final report of the overall study findings. We will also put a project summary on the Centre for Community Child Health website.

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

Name: Karen Wirth

Contact telephone: (03) 9345 6528 or scout.study@mcri.edu.au

You can also find out more about SCOUT at <http://www.rch.org.au/ccch/scout>

If you have any concerns about the project or the way it is being conducted, and would like to speak to someone independent of the project, please contact:

Head of Department
Ethics and Research Department
Human Research Ethics Committee
Telephone: (03) 9345 5044



**CONSENT FORM FOR PARENT/GUARDIAN TO GIVE INFORMED CONSENT
FOR THEIR CHILD TO TAKE PART IN A RESEARCH PROJECT**

HREC Project Number: TBA

Research Project Title: The SCOUT study: Statewide Comparison of Outcomes of Hearing Loss

Researcher(s): A/Prof Melissa Wake, Dr Teresa Ching, Ms Lisa Gold, Dr Zeffie Poulakis,
Prof Field Rickards, Prof Sheena Reilly, and Ms Karen Wirth.

I (Parent/Guardian name) _____

voluntarily consent for my child (name) _____ to take part in the above research project explained to me in writing by Dr Melissa Wake and Ms Karen Wirth

- I believe I understand the purpose, extent and possible effects of my child's involvement in this project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that the researcher has agreed not to reveal results of any information involving my child's medical history, subject to legal requirements.
- If information about this project is published or presented in any public form, I understand that the researcher will not reveal my child's identity.
- It has been explained that my child's involvement in this project may not be of any benefit to him or her.
- I understand that if I refuse to consent, or if I withdraw my child from the project at any time without explanation, this will not affect my child's access to the best available treatment options and care from The Royal Children's Hospital.
- I understand that this project follows the guidelines of the National Statement on Ethical Conduct in Human Research (2007) and has been approved by the Royal Children's Hospital Ethics in Human Research Committee and the National Acoustic Laboratories Ethics Committee.

Signature of parent/guardian _____ **Date** _____

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Research team to complete on return from the parent:

We have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their child's involvement in this project.

Researcher's Signature _____ **Date** _____

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