

PARENT/GUARDIAN INFORMATION STATEMENT **AND CONSENT FORM**

HREC Project Number: 31081

Research Project Title: VicCHILD: the Victorian Childhood Hearing Impairment Longitudinal Databank

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Thank you for taking the time to read this Information Statement. This Information Statement and Consent Form is 6 pages long. Please make sure you have all the pages.

We invite your child to take part in a research project, explained in detail below.

What is an Information Statement?

These pages tell you about the research project. They explain to you 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.

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 - this won't affect their access to the best available treatment and care from The Royal Children's Hospital.

Once you understand what the project is about, you can decide if you would like your child to take part. If yes, please complete and sign the consent form at the end of this information statement. There is a second copy of the consent form for you to sign and keep, along with this information statement.

1. What is the research project about?

The VicCHILD project aims to advance research about childhood hearing loss. It started in 2011 and is based at The Royal Children's Hospital, Melbourne. We hope it will help understand what leads to the best outcomes for these children. In turn, this may lead to better counseling and treatment.

VicCHILD's full name is the '**V**ictorian **C**hildhood **H**earing **I**mpairment **L**ongitudinal **D**atabank'. It is a databank for children born with permanent hearing loss. A databank is a special kind of research database. It keeps recruiting children indefinitely, and stores their information confidentially for many years.

Databanks have special advantages. They can:

- Answer questions that need very large numbers of participants.
- Answer new research questions quickly using the stored information.
- Show how children's outcomes change over time, as new treatments and approaches develop.
- Find all children who are eligible for new research projects, so they have the chance to take part.

VicCHILD pulls together different kinds of information into a single databank. Most of this information is already collected – we just need your permission to access it. Its value comes from joining it up in new ways. This means that VicCHILD doesn't need to make big demands on you or your child.

You may choose to provide some or all of the information listed in Section 4 and 5 to VicCHILD. VicCHILD is open to children with a permanent hearing loss from birth or soon after. Around 60 to 100 babies are joining the databank each year. Later, it may expand to other Australian states and territories. Some other countries are also interested in joining.

2. Who is funding this research project?

The Murdoch Childrens Research Institute (MCRI) and the Centre for Community Child Health at the Royal Children's Hospital.

3. Why are we being asked to be in this research project?

The Victorian Infant Hearing Screening Program (VIHSP) has passed on your information as your child was identified as having a hearing impairment.

4. What do we need to do to be in this research project?

VicCHILD would like to contact you every 5-7 years. We hope to re-contact families around the start and end of primary school, and around the end of high school.

The VicCHILD project is made up of parts – you may want your child to be in all parts, or only some parts. It collects some information directly from families. It also gathers information from other sources, with your permission. This means we collect accurate information without a great deal of your time.

To take part in the VicCHILD project, your child will need to complete:

- A questionnaire every 5-7 years, once he/she is old enough. It is short, taking around 15-30 minutes. It asks about your child's own well-being and quality of life. For younger children a VicCHILD researcher may help. Older children can fill out the questionnaires themselves.
- An assessment of language and learning, starting from age 5-7 years. We aim for a VicCHILD researcher to assess your child at ages 5-7 years, 10-12 years and 15-17 years. This depends on VicCHILD's resources being available to do the assessment. It takes about 1-1½ hours, depending on your child's abilities. We use standard tasks suited to the child's age. For example, we show pictures and ask questions, then listen to their answers and their speech. The tasks are short and varied, and most children enjoy them greatly. If you agree, we may audio- or video-record parts of the assessment to help with scoring and the recordings also become part of the databank.

To take part in VicCHILD, you will need to complete:

- A questionnaire mailed to you every 5-7 years: This takes about 15-30 minutes to fill out. You can post it to us, or we might collect it when we visit. It asks about your child, and about you and your family.
 - *About your child*: We ask about your child's health, quality of life, language and learning. We also ask about the services your child uses, and your experiences with these services.
 - *About you and your family*: We ask about your family history and demographics (where you live, your current work etc.). We also ask about your own health and feelings, and how your child's hearing loss has affected your family.
- A 1-1½ hour home visit soon after each questionnaire: We make a time for a researcher to visit you at home. If you prefer, the visit could be somewhere convenient to you (like childcare or school), or you can come to the Royal Children's Hospital. At the visit:
 - The researcher goes through any consent forms needed at that time, to make sure you understand about each part of VicCHILD. You can ask questions that you may not have thought of at the first phone call. Then you can consent to the aspects of VicCHILD you want to take part in.
 - We may ask you to complete a second short questionnaire. This covers your child's development, and more detailed questions about the services your child uses and their costs to you. The researcher can help you, or you can complete it by yourself. The researcher sees your child (see section above).

If a visit isn't possible, we can interview you by phone instead. However, it's not possible to collect all of the information over the phone.

5. What are other ways I can take part in VicCHILD?

You can give permission for your child to take part in some or all parts of VicCHILD. The following parts of VicCHILD are optional. They don't require you to do anything. With your permission VicCHILD will carry them out on your behalf.

We would like to get your permission for VicCHILD to:

A. Link your child's information with other existing datasets ("data linkage/data retrieval")

As Australian children grow up, services and agencies collect and store information. It's used for purposes like budgets and reports about Australians' health and education. It is carefully protected and confidential.

You can give permission for VicCHILD to access some of the information stored about your child. It may relate to your child's hearing loss, its diagnosis and cause; devices to assist hearing; the services children use; their progress; and demographic information.

Below, we list the main organisations that store these data. Some of these are only available as your child gets older. Also, most children don't have information with every organisation.

- Organisations:

Victorian Perinatal Data Collection; Victorian Birth Defects Register; Victorian Infant Hearing Screening Program (VIHSP); Medicare/PBS (Pharmaceutical Benefits Scheme); Australian Hearing; Hospital Admissions data; Royal Victorian Eye and Ear Hospital records & Cochlear Implant Clinic records

- Sources of data:

School Entry Health Questionnaire; Australian Early Development Index; National Assessment Program – Language and Literacy (NAPLAN); Victorian Certificate of Education/ Victorian Certificate of Applied Learning (VCE/VCAL)

Over time there may be other databases that could help hearing research. We are also asking your permission to access such information. This would also need approval from the Ethics Committee.

We retrieve information in one of two ways. This depends on the organisation that holds the data.

- *Confidential data retrieval:* VicCHILD sends a request to the organisation. The request includes your child's name, birth date, or other details needed to identify your child's records. The organisation then gives the information directly and confidentially to the VicCHILD researchers.
- *Re-Identifiable linkage:* Linkage is done confidentially by VicCHILD researchers, or by ethically-approved data linkage organisations like Biogrid or the Victorian Data Linkage Unit. Your child's personal information is stored separately and given a unique linkage code. This code allows linkage and updates of your child's data, as more information is collected. Only the research team has access to this code.

B. Access and collect biological samples from you and/or your child

We would like to access two samples from your child.

- Your child's newborn screening ("Guthrie") card. This dried blood sample was collected from your child's heel soon after birth. It is stored by the Victorian Clinical Genetics Service at the Murdoch Childrens Research Institute. It can be studied for factors that might influence hearing, like viral infections during pregnancy. It can also be used for genetic analysis.
- A genetic sample via a buccal (cheek) swab or saliva sample. This lets us study genetic causes of hearing loss. These samples are securely stored in locked freezers at the Biorepository Facility of the Murdoch Childrens Research Institute for the duration of VicCHILD. Collecting the sample is very simple – it doesn't hurt at all and takes about a minute to do.

We would also like to access Mother's prenatal test, if available.

- Most mothers have a blood test when they are 10-12 weeks pregnant, to screen for conditions like Down Syndrome. The serum is currently stored by the Victorian Clinical Genetics Service at the Murdoch Childrens Research Institute. The baby's mother can give permission to access it. It could address factors very early in pregnancy that might influence how hearing develops.

C. Exchange of information

Sometimes, two agencies may ask to see your child around the same time. For instance, we might contact you soon after a school entry assessment. Or a secondary school might request results from the VicCHILD 10-12 year old assessment. To avoid multiple assessments, you can let us exchange results with other professionals (like speech pathologists, audiologists, and teachers). This might be by letter or phone.

D. Re-contact you for new research projects

Over time, knowledge grows. This can lead to new research questions, and perhaps new research

projects of interest to you. This might involve new technologies and/or new treatments, beyond the information you already provide to VicCHILD. If you give permission, we can contact you when we learn of a new project that might suit your child. You could find out more and then decide if you wanted to take part. You would then decide whether or not to consent to any new projects.

The project might be with VicCHILD researchers or with other research teams. If the new research was with a different research team, we would send you an invitation letter on their behalf. We only pass on your contact information if you agree to this.

E. Use your child's VicCHILD data for future/other research projects (data sharing)

VicCHILD is a resource for researchers around Australia and internationally. They can request access to data to answer different research questions. This ensures that your valuable information is used to the full. Any such requests need to be approved by the VicCHILD team, and the research must be ethically approved. Researchers can access only the data items they need from VicCHILD. When they use your child's VicCHILD data, they would not be able to identify you or your child.

We would also like to be able to join your VicCHILD information with larger data repositories to answer questions about language or hearing. For example, Professor Melissa Wake, VicCHILD's Chief Investigator, is also a lead researcher in the MCRI's "*Centre of Research Excellence in Children's Language*" (CRE-CL). Families from several of the MCRI's large language studies have agreed that their data can be pooled into a single large databank for the CRE-CL. This makes a much bigger dataset containing children's language assessments than any one project could manage by itself. We hope this will lead to major new discoveries about how children learn language, with or without hearing loss. To do this, we need to share some identifying information with the CRE-CL administrators. However, this doesn't go in the dataset, so researchers using your data are not able to identify you or your child.

6. What are our alternatives to taking part in this project?

You don't have to take part if you don't want to. If you consent and then change your mind, you can withdraw at any stage. This won't affect any care or treatment your child receives from The Royal Children's Hospital.

If you decide to withdraw, we would like to keep the information collected up to that point. However, if you don't want us to keep the information, you can tell us when you withdraw. Then we would remove your child's information and destroy it.

7. What are the possible benefits for my child?

Your child may not directly benefit from taking part in VicCHILD. However, in the long-term, the project may lead to better treatment for children with hearing impairments. This might benefit your child.

If we assess your child's language, you can ask us for a short report of the results.

We may offer you or your child the chance to be in other research projects. These may or may not benefit your child. You would choose at the time whether to join any extra projects we tell you about.

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

Knowledge from VicCHILD may help other children with hearing loss in the future. This might be through better diagnosis, counselling, treatments or interventions. These could improve children's speech and language, learning, and well-being.

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

We don't expect any harm to you or your child. Answering questionnaires may cause you to think of new questions about your child's hearing condition. You might not have thought of these before. If so, we encourage you to contact your GP, paediatrician or ENT specialist. You can also contact VicCHILD.

There is always a risk to privacy when keeping a databank, particularly with ongoing data storage. However, we have strict privacy and confidentiality policies to minimise this risk. If you have any questions or concerns about the VicCHILD project, please contact us at any time. Our phone number and email are at the end of this statement.

10. What are the possible inconveniences?

The main inconvenience is to your time. Each parent questionnaire takes about 15-30 minutes. A first visit when your child is a baby takes about 30 minutes. Visits to assess your older child take around 1.5 hours. We hope these visits and questionnaires will happen every 5-7 years (this does depend on ongoing funding).

11. How do I know my child's information is confidential?

All the information you give us is private. We can only disclose it according to the consent that you give us, except as required by law. In accordance with Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access your information.

Information collected by VicCHILD is re-identifiable. This means we remove your names and use a special code number instead whenever your child's information is analysed. That way, your child's identity is always protected. However, VicCHILD can still go back and match your names to your VicCHILD code number for administrative purposes, if needed.

Questionnaires are stored in locked filing cabinets at the Murdoch Childrens Research Institute or a secure storage facility. Genetic samples are stored in locked freezers at the Biorepository Facility of the Murdoch Childrens Research Institute. All information is stored on a password-protected computer database.

We plan to present results at conferences and in professional journals. We only report information for groups of children - no one will be able to identify you, your child or your family.

12. Will we be informed of the results?

VicCHILD is building up slowly, as children are born and join the project. We can begin to study the information once the databank has been running for 2-3 years. We mail a newsletter each year to families. We also have a VicCHILD webpage. It contains information about VicCHILD and in time will also hold newsletters and links to research publications.

We won't routinely send you results of your child's language and learning assessments. However, you can ask us for a short written report if you would like one.

13. Who are the researchers?

Professor Melissa Wake, a paediatrician, is Director of Research at the Centre for Community Child Health.

Dr Zeffie Poulakis, a psychologist, is the Director of the Victorian Infant Screening Program (VIHSP).

Dr Kathryn Mueller, a research officer in the Hearing, Language and Literacy Group at the MCRI.

Dr Rachel Burt, a senior research fellow at the MCRI, is group leader of the Molecular Hearing Group.

Professor Jane Halliday, an epidemiologist, is head of the Public Health Genetics Group at the MCRI.

Mr Luke Stevens is the Data Management Coordinator at the MCRI.

Ms Sherryn Tobin, a provisional psychologist, VicCHILD's senior research coordinator.

(Over time, the research team may change, as VicCHILD and its participants grow.)

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:

Names: Sherryn Tobin
Contact telephone: (03) 9345 4215
Email: vic-child@rch.org.au
Website: http://www.rch.org.au/ccch/for_researchers/VicCHILD/

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:

Director, Ethics & Research, The Royal Children's Hospital on telephone: (03) 9345 5044.

