

## Appendix B – Participant Information Sheet



THE FACULTY OF SCIENCE

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*Te Kura Matai Hinengaro*

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### PARTICIPANT INFORMATION SHEET

**To:** Parents, caregivers, or whānau happy for their child to take part in a study looking at a new way to test hearing. Some specialists work in clinics (clinicians) and test the hearing ability of infants and children. When playing two or more different sounds to infants, these clinicians cannot test yet, if babies and young children can hear whether they are different. Also, infants and young children cannot easily tell us what hear. A new test will help us learn if babies and young children can hear whether two or more speech sounds are different from each other. Test results for speech-like sounds may later be used to fine-tune hearing aids for children with hearing loss, towards improved learning and communication.

**Project title:** A reliable and feasible method for providing objective assessment of auditory discrimination; the optimised Mismatch Response (MMR)

**Principal Investigator:** Professor Suzanne Purdy (Head of School, Psychology)

**Co-Investigator:** Dr Kim Wise (Audiologist; Research Fellow)

**Co-Investigator:** Dr Michael Maslin (Audiologist; Research Fellow)

#### Researcher introduction

The research project is under the supervision of Professor Suzanne Purdy (Head of School, Psychology), with logistical input and guidance from Co-Investigator Dr Michael Maslin, an Audiologist and Research Fellow. The test results will be collected by Co-Investigator Dr Kim Wise, an Audiologist Research Fellow working with the Speech Science Group, School of Psychology, Faculty of Science, Grafton Campus. Funding for this study is supplied by a research grant awarded by the William Demant Foundation.

#### Project description and invitation

This study aims to look at signals in the brain made by the hearing pathways, when sounds are heard. One special group of brain signals made by the hearing pathways is known as 'cortical auditory evoked potential' (CAEPs). They are called 'cortical' because the signals come from the brain. They are called 'auditory' because the signals are made by the hearing

(or auditory) pathways of the brain. They are called ‘evoked’ because these signals are caused when sounds are picked up or ‘heard’ by the hearing pathways of the brain.

One particular type of CAEP brain signals made by the hearing pathways is the Mismatch Response (MMR). The MMR shows a special type of brain activity that happens when two or more different sounds, are also heard to be different. The MMR can be encouraged to happen and tested, when a group of similar sounds are presented or played one after the other (commonly-occurring) but, is sometimes occasionally interrupted by a different sound (rarely-occurring). The presence of the MMR shows the hearing system’s ability to not only ‘hear’ the sounds but its ability to also notice the rarely-occurring sound was different. MMR test results for speech-like sounds may be used to find out if certain differences in speech sounds can be noticed by the hearing system. Unfortunately, the way the MMR has been tested in the past tends to take too long, making it unsuitable for infants and young children.

For infants younger than 6 months with hearing loss who need hearing aids, there is a lack of tests for this age group that tell us whether they can pick up certain differences in speech sounds, when wearing their hearing aids. When an infant is at least 6 months old or older, their hearing can be more reliably tested with methods that are ‘behavioural’ – that is, the child is old enough to turn their head towards a sound they hear with their hearing aid(s). Until then, an infant must be tested with methods that are ‘objective’ – that is, there is no movement or response needed from the child. The use of CAEPs and the MMR are considered ‘objective’, as the brain signals only happen if the sounds are heard (like with CAEPs) or if the sounds also noticed to be different from one another (like for the MMR). As the way the MMR has been tested in the past tends to take too long, we must wait until an infant with hearing loss is old enough to do behavioural testing with their hearing aids. This means that until then, the hearing aids may not be well-tuned for the child to hear the differences in speech sounds needed for learning and communication.

Our research group is aware of some international research that has shown a way to shorten the time it takes for MMR testing. This shorter MMR method is called the ‘optimised’ MMR. Instead of introducing just one rarely-occurring different sound among a group of commonly-occurring, similar sounds, the optimised MMR occasionally interrupts the commonly-occurring sounds with *two or more* rarely-occurring different sounds. This speeds up MMR testing and lets the clinician test the hearing system’s ability to notice differences between several sounds, during one test session. We have already successfully tested the optimised MMR method with normally-hearing adults. We aim to test the new optimised MMR method with infants. This would include observing and comparing how well the optimised MMR method works with normally-hearing infants, and infants with hearing loss in both ears.

The **Project Procedures** are detailed below. There are 2 groups of infants we are interested in, for taking part in this research study. One group of infants (Group 1) will have normal hearing. That is, these infants had the newborn hearing screening at birth and were found to have no hearing concerns, or there were some concerns with the newborn hearing screening, but further hearing testing showed normal or near-normal hearing. A second group of infants (Group 2) will have hearing loss in both ears. This hearing loss will have been picked up by the newborn hearing screening at birth and/or confirmed by further

hearing testing. Having both groups of infants (Group 1 and Group 2) allows the researchers to observe and compare, how well the optimised MMR method works for both groups and to get a start on gathering information on how these groups typically perform with the optimised method.

The study will be looking for infants who are 3 to 12 months of age. Infants taking part in this study should have normal head/brain health (that is, no birth or head injury-related issues), no current ear infections, or issues with ear wax. As mentioned above, there are 2 groups of infants we are interested in, for taking part in this research study. Those with normal hearing (forming Group 1) and those with hearing loss in both ears (forming Group 2). The Project Procedures highlighted below, are the same for normally-hearing infants and for infants with hearing loss in both ears. Both infant groups will experience the same research tests and activities. There is no difference in how the groups will be managed. There is no treatment involved in this study. This study only seeks to observe how well the optimised MMR characterises hearing abilities for both groups.

### **Project Procedures**

Parent(s)/caregiver(s), and whanau interested in their child being involved in the study will be asked to read and sign a consent form. By signing the consent form, you indicate your understanding of this Participant Information Sheet, you agree to sharing any previous hearing tests or hearing health information on file for your child, you agree to a brief talk that will cover your child's hearing, health, and growth after birth, and you also agree to the clinician doing some standard pre-tests for hearing wellbeing with your child. These pre-tests are described below in the ***Audiological Assessment*** section.

The testing for which your child would need to be present for, would happen over **one, one-and-a-half-hour** session for the study. You and your child would have the option for a comfort break after the standard pre-tests for hearing wellbeing, and before the MMR testing. Extra breaks can be supplied as needed.

### ***Audiological Assessment (standard pre-tests for hearing wellbeing):***

This involves:

1. Brief developmental history
2. Brief otological (ear and hearing) history
3. Otoscopic examination (visual examination of the ear canal using a hand-held ear light)
4. Tympanometry (middle ear health check)

The standard pre-tests for hearing wellbeing will be carried out according to New Zealand Audiological Society (NZAS) Best Practice Guidelines (2016).

Infants should be fed beforehand. Additional feeding could be considered during the break between the audiological assessment and set-up of MMR testing, as it is ideal to finish the MMR test once the recording set-up is complete. It is unlikely your child will need a break once the

MMR testing starts as they should be relaxed and held/seated comfortably on the parent's/caregiver's lap. However, comfort breaks can be scheduled as needed.

Infants should not have hair conditioner applied to their hair near the skin of the head (scalp) the night before or morning of the MMR testing session. Small, electronic sensors will be placed on the child's forehead, behind the ears, and on top of the head. These sensors pick up the MMR signals from the hearing pathways in the brain. The use of hair conditioner can make it difficult for the electronic sensors to stick to the scalp properly. The electronic sensors are regularly used in typical hearing screening and hearing tests involving infants. Also, your child should not be exposed to loud noise 24 hours prior to testing (that is, louder than your average household vacuum), as that may cause temporary changes in hearing ability.

***Evoked Potential (MMR) Testing and Recording:***

The MMR testing and recordings will take place in a special room designed for the test recordings. Infants taking part in the study will be held/seated on the parent's/caregiver's lap, as the parent's/caregiver's sit in a comfortable reclining chair for the duration of the testing. Whānau, parent(s)/caregiver(s) will be talked through the MMR testing method. They will have a chance to ask questions and have them answered. The small electronic sensors (electrodes) will be placed onto the locations around the head described above (forehead, behind the ears, and the top/centre of the head). The sensor sites will need to be prepared. The preparation involves gently rubbing the skin with a gel that is removable with water and often used in hearing clinics. There is a small risk of discomfort but, this is likely to be brief. Direct contact will be maintained with the infant, and their whānau, parent(s)/caregiver(s) present, at all times. A research assistant will be present in testing area, throughout the MMR procedure.

Four, small electronic recording sensors will be placed around the infant's head as detailed above. A range of commonly-used speech sounds such as [/m/ as in **man**, /g/ as in **gab**, /t/ as in **tab**, and /s/ as in **sad**] will be used to encourage the MMR to happen. The speech sounds will be played through a loudspeaker at a comfortable volume, that is similar to the level of a typical conversation. Infants taking part in the study who remain awake will have their attention held by toys displayed to them by a research assistant. However, the MMR has been shown to be reliably recorded in sleeping infants as well.

***Post-recording:***

The gel used to prepare the skin for the placement of the small, electronic sensors will be removed with tissue at the end of the test. A summary of the results will be available for the Whānau, parent(s)/caregiver(s) if desired, additional time is available for any questions about the test results or the research project.

Parent(s)/caregiver(s) will receive a **petrol voucher worth \$20** at the end of the session to help pay for any travel costs and as an offer of appreciation for their child taking part in the study.

All of the research procedures described above **will take place in the Greenlane Clinical Hospital Audiology Centre, Auckland New Zealand:**

214 Green Lane West  
One Tree Hill, Epsom,  
Fourth Floor  
Auckland 1051

### **Tikanga Māori protocols**

If you require Māori cultural support, talk to your whānau and/or iwi in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 42324. You are also welcome to discuss or highlight any concerns arising with the testing with the clinician at the time.

### **Anonymity and Confidentiality**

Infant test results collected for the study will be de-identified. In any report of the data, information, or results, the identity of any infant taking part in the study will not be revealed.

### **Data storage/retention/destruction/future use**

During the project data, information and test results will be recorded using written documentation and in software.

Infants taking part in the study will be identified by a number given to them, which will appear on these records. A separate record of participants' names and their allocated number will be kept secure during the project and will be destroyed immediately after project completion, along with all other personal information which may identify individuals. Only non-identifiable information required for analysis of the results will be kept and stored for 6 years before being destroyed. Non-identifiable group data will be securely kept until no longer needed by the University. The consent form will be kept secure and separate from the data by the Principal Investigator for 6 years, per current University research practise, before being destroyed.

### **Risks**

The optimized MMR test and recording method is low-risk as it is already in research use involving adults, children and infants overseas and in NZ (for adults). There may be mild discomfort with the set-up for the MMR recordings – the skin is gently rubbed/exfoliated with a gel (Nuprep) which is hypoallergenic, dissolves in water, but is mildly scratchy. It may be slightly irritating on the skin during test preparation but this should subside quickly. Sounds played will be of a conversational level and pose no risk of loudness discomfort or unhealthy noise exposure.

### **Incidental findings**

If there is an unexpected hearing problem found on the day of testing, the infant participants' Parent(s)/caregiver(s) will be informed, with support and proper referrals supplied by an experienced audiologist. The Principal Investigator and the Co-Investigators are experienced, clinical audiologists and may advise GP referral depending on the case. As this study requires normal-hearing participants, or infants with hearing loss affecting both ears, in the case of an incidental finding such as an unexpected ear problem (for example, an ear infection or similar), an infant may not be suitable for the study and may not proceed to testing. However, a petrol

voucher would still be provided given the time and travel associated with the pre-tests for hearing wellbeing.

### **Right to Withdraw from Participation**

- The parent(s)/caregiver(s) are free to stop/remove their child from being a part of this study at any time without giving a reason. They are free to remove any information linked to their child up-to 1 February 2022. If they do stop/remove their child from being a part of this study their child's future health care will not be affected.

### **Compensation**

In the unlikely event of a physical injury as a result of your child taking part in this study, you may be covered by ACC under the Accident Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or nonearner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If ACC cover is received, generally this will affect your right to sue the study's investigators. If you have any questions about ACC, contact your nearest ACC office or the study's investigator.

You are also advised to check whether having your child take part in this study would affect any indemnity cover you have for your child or are considering, such as medical insurance, or life insurance.

### **Contact Details**

Further questions regarding the research project may be directed to:

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For concerns of an ethical nature, you may contact the Chair of the Auckland Health Research Ethics Committee at:

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or at:

(09) 373 7599 ext. 83711,

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