HREC Project Number: 71941

Short Name of Project: fNIRS in children

Full Name of Project: The use of functional near-infrared spectroscopy to assess infant hearing and language development.

Principal Researcher: Professor Colette McKay, Principal Scientist and Leader of Translational Hearing Research

Version Number: #2 **Version Date:** 01/04/2021

Thank you for taking the time to read this **Parent / Guardian Information Statement and Consent Form**. We invite your child to take part in a research project that is explained in this form.

This form is 7 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information Statement and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not your child takes part in the research project. You do not have to agree if you do not want to.

Signing the form

If you want your child to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- Understand what you have read
- Had a chance to ask questions and received satisfactory answers
- Consent to your child taking part in the project.

We will give you a copy of this form to keep.

1. What is the research project about?

The introduction of newborn hearing screening along with improved hearing instrument technology has led to much better average language development in children with hearing impairment, which has important life-long social, educational, and vocational benefits. However, in spite of these advances, there is still great variability in the language development of children with hearing impairment. We know that early hearing is crucial for the development of the brain's language areas, and that is why infants as young as two months old are receiving hearing aids and cochlear implants.

But how do we know, in a young infant, whether the hearing aid or cochlear implant is programmed optimally to provide the best access to speech sounds, or whether these infants' brains are developing the necessary language areas like their normal hearing peers? Since babies cannot tell us these things, we must 'wait and see' whether language develops at an older age—we alter the hearing aid program, or the hearing therapies, over time as the baby grows. This project is developing a new way to answer the above important questions at an earlier stage, so that the hearing aid works optimally right from the start and we can determine early on whether language areas in the brain are developing normally.

fNIRS (or functional near-infrared spectroscopy) is a child-friendly brain imaging technique that uses lights to record brain activity. The photo on the left shows a baby wearing a cap that holds the light sources and detectors. The light is similar to that used in hospitals (usually in a peg on your finger) to check the oxygen level in your blood. It does not have any effect on your brain and you cannot feel it.

Currently, audiologists often use a test called auditory evoked potentials to measure whether a child can hear a sound. However, the current technology has various limitations that make it unsuitable in some situations.

This project will investigate how fNIRS can overcome those limitations, and provide the audiologist with the detailed information required to provide every infant with the best hearing aid and settings for their individual needs.

2. Who is running the project?

The project is being conducted by the Bionics Institute, and will take place at the Bionics Institute in East Melbourne (384-388 Albert St, East Melbourne VIC 3002). The project is being conducted by Professor Colette McKay and is funded by a National Health and Medical Research Council Development grant, as well as a fellowship from the Garnett Passe and Rodney Williams Memorial Foundation.
The test protocol was written and developed by members of the Bionics Institute Hearing Research Team. The team consists of scientists, engineers, audiologists and postgraduate students.

3. Why is my child being asked to take part?

Two main groups of infants up to two years of age are taking part in the study: those who have normal hearing (and who have passed newborn hearing screening) and those who have been diagnosed with a hearing impairment, including infants who have been diagnosed with auditory neuropathy.

The results from infants with normal hearing will help us to fine-tune the way that the fNIRS hearing test works. The results from infants with hearing impairment will help us to find out whether the fNIRS test provides useful information about each child's hearing. A group of adults with normal hearing will also participate so that we can make sure that the fNIRS tests are efficient and work well.

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

Your child will attend 1-2 sessions for fNIRS measurements at the Bionics Institute. Since this study is intended to answer several research questions, you may be invited to bring your child back for one or more further sessions at your convenience, but this will not be obligatory. If you can only come for one session, that is still very useful for us.

At the start of the first session, you will be asked some questions about your child's hearing and basic health, and your child's ears will be checked. If your child's hearing is unknown or uncertain, a hearing assessment may be carried out, in which sounds are played and your child's responses rewarded with social feedback and interesting video clips.

For the fNIRS test, your child will listen to different sounds while wearing the fNIRS cap. If he/she has a hearing device, they may also be tested whilst using their hearing device. Younger Infants will be tested in a natural sleep condition. Older infants will be tested while watching an interesting visual animation. You will hold your child while sitting in a comfortable armchair.

A speech sound hearing test may also be conducted in the same or additional session to the fNIRS test. For this test, your child will be seated comfortably on your lap and listen to sounds. Your child's responses to the speech sounds will be rewarded with social feedback and interesting video clips.

If your child has a hearing impairment, you will be asked to provide permission for us to obtain a copy of previous hearing assessments, and details of the hearing device your child, from Hearing Australia or your child's audiology clinical manager.

Some infants with a hearing impairment will be invited to attend an additional session in which the child's hearing will be assessed using the evoked potential measurements that are currently used in audiology clinics. For this test, little electrodes will be placed on the child's head to measure the tiny electrical signals that the brain emits when listening to sounds. Again, your child will be held comfortably on your lap in either a natural sleep state or quietly awake watching a video.

5. Can my child stop taking part in the project?

Your child can stop taking part in the project at any time. You just need to inform us. You do not need to tell us the reason why. If your child leaves the project, we will use any information already collected unless you tell us not to.

6. What are the possible benefits for my child and other people in the future?

No direct benefit will be obtained for your child by participating in this research. If your child has a hearing impairment, participating in this research will not alter the management of your child by his/her managing audiologist. If this research project is a success, a clinical trial of the new fNIRS test in audiology clinics will be conducted at a later time. In the longer term, we hope that the new tests will result in improved language development for infants born with a hearing loss.

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

This research does not involve any intervention or medical treatments. The fNIRS equipment and measurements have been used in many research studies with children and babies, and do not involve any known risks to you or your child. All sounds used will be within a comfortable range of loudness for each child. We are aware that some infants or children dislike wearing caps or hats, and in that case the fNIRS measurements will not proceed if the child cannot be made comfortable with wearing the cap. We will make the test sessions as pleasant an experience as possible.

While the risk of injury is unlikely, if you or your child 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.

8. Termination of the study

This research project may be stopped unexpectedly for a variety of reasons e.g. failure of the equipment. If this happens we will inform you of any implications that may affect your child.

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

By signing the consent form, you agree to the research staff collecting and using personal information about your child for the research project and any follow-on study that uses the data we collect for this study. Additionally, your child's results from this study may be made available to other researchers, as required by many publishers and grant funding bodies.

For infants with hearing impairment, the personal information used in this study will include the child's age, hearing history, the cause of hearing loss (if known), current cochlear implant or hearing aid programs, and latest hearing assessment test results from your child's hearing clinic, as well as the results from the research sessions.

Any information obtained in connection with this research project will be 'de-identified' – i.e. your child's results and other information will be assigned a unique ID code, and their name and other potentially identifying information (e.g. address, contact details, clinical manager, unusual aetiology, etc) removed from the information. The information needed to connect the ID code to your child will be kept in a secure place separate from the other information and will be destroyed once the project, or follow-on study, is completed. If we share the study information and results with external researchers, they will only have access to de-identified information. This means that no-one except the team members on this project will be able to connect your child's data to his/her name without your request and permission, except as required by law.

While the project is in progress, study information will be stored electronically on secured Bionics Institute servers, to which only Bionics Institute staff who directly work on this project will have access. Additionally, our laboratory note books will be kept in locked filing cabinets. All information (including consent forms) will be retained according to the Bionics Institute data retention policies for a period of 10 years, after which the paper records will be shredded and electronic de-identified data archived in the Bionics Institute's secure data archive system.

It is anticipated that the results of this research project will be published and presented in a variety of forums. In any publication or presentation, information will be provided in such a way that your child cannot be identified. This will be achieved by using your child's unique ID code, rather than his/her name. No link between the ID codes and your child's name will be shared in these publications or presentations. If you do not want your child's de-identified information to be shared with external researchers, you should let us know and we will make sure that it is not shared.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your child's 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.

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

The results of this project will be published in scientific journals. We will also make available to you a plain English version of the results. Please let your researcher know if you would like to receive a copy of this report in the mail or by email.

11. New information arising during the project

During any research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researchers will discuss whether this new information affects you and your child. This new information may mean that your child can no longer participate in this research. If this occurs, the person supervising the research will stop your participation. 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 researchers might consider it to be in your best interests to withdraw you and your child from the research project. If this happens, he/she will explain the reasons.

12. 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 Children's Hospital Melbourne.

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.

13. Participation is voluntary

Participation in any research project is voluntary. If you and your child 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 and your child 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 child's routine treatment, your relationship with those treating your child, or your relationship with the Royal Children's Hospital or Hearing Australia.

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.

14. Future Research

We would like you to consider allowing us to send you information about new research projects that may be suitable for your child. The information we send will give you the full details about the project. It is your choice whether your child takes part in these projects. You can say no to them if you want to.

15. Who should I contact for more information?

If you would like more information about the project, please contact:

Name: Professor Colette McKay

Contact telephone: +61 3 9667 7500

Email: cmckay@bionicsinstitute.org

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your child's rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

CONSENT FORM

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- I have read this information statement and I understand its contents.
- I understand what my child and I have to do to be involved in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Optional consent

☐ I do	☐ I do not	Consent to be contacted about future hearing research projects that my child may be suitable for.

Child's Name

Parent/Guardian Name	Parent/Guardian Signature	Date
Name of Witness to Parent/Guardian's Signature	Witness Signature	Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above. I believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name	Research Team Member Signature	Date

Note: All parties signing the consent form must date their own signature.