AUDIOLOGIST INFORMATION AND CONSENT FORM

Project Number:	90457
Short Name of Project:	fNIRS to improve early intervention
Full Name of Project:	Improving early intervention in hearing impaired children using functional near-infrared spectroscopy (fNIRS)
Principal Investigator:	Professor Colette McKay
Version Number:	3 **Version Date:** 13/04/2023

Thank you for taking the time to read this **Participant Information and Consent Form**. We are inviting you to take part in a project about the use of a new hearing test (fNIRS) to improve early intervention for infants with hearing loss.

This form is 5 pages long. Please make sure you have all the pages.

What is an Information and Consent Form?

An Information and Consent Form tells you what the project involves. It helps you decide whether or not you want to take part in the project. Please read it carefully. Before you make a decision, you can ask us questions.

Taking part in the project is up to you

You get to choose whether or not to take part in the project.

If you decide you do not want them to take part, this is ok. It will not affect your relationship with the Bionics Institute.

Signing the form

If you want to take part in the project, 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 taking part in the project.

We will give you a copy of this Information and Consent Form to keep.

1. What is the project about?

We are inviting you to take part in a project called ***fNIRS to improve early intervention*** ('the project'). fNIRS is a baby-friendly technology that uses near-infrared light to image the response of a brain to stimuli such as sounds. We have developed an fNIRS hearing test that can test whether an infant can both hear and tell the difference between speech sounds, with over 95% accuracy in individual babies.

Our project aims to find out if the results provided by our new fNIRS hearing test help audiologists when making decisions at various key points along an infant's hearing care pathway. As paediatric audiologists you would be familiar with those key questions:

- Does the baby need hearing aids?
- Are the hearing aids providing the sound necessary for speech and language development?
- Would a cochlear implant be better?
- How can you objectively program a cochlear implant?

You would also be familiar with the challenge of providing answers and recommendations to parents/guardians based on the relatively limited evidence sometimes provided by standard audiological tests.

We are conducting a clinical trial where we recruit infants who are still progressing through their hearing care pathway. We will:

- Obtain each baby's standard hearing test results and put them in summary form so the clinic or the baby cannot be identified;
- collect fNIRS test results from each baby;
- ask independent audiologists (who are not involved in the baby's care) to look at the baby's hearing results with or without the additional fNIRS test result and tell us what they would recommend as the next steps, and how confident they are about the recommendations;
- compare how confidently the audiologists can make the next step recommendations with or without the inclusion of fNIRS results.

As one of the independent audiologists, you will not know the infants whose test results you are assessing, and your decisions will not influence the care the baby receives from their managing audiologist or service.

Separately from the participation of the independent audiologists, the fNIRS test results will be provided to the baby's managing audiologist with the parent/guardian's permission. All participating babies are therefore potentially able to benefit from the information the fNIRS test provides.

The fNIRS hearing test is an experimental test. This means that it is not an approved test for hearing in Australia or other parts of the world. Its clinical usefulness needs to be evaluated so that it can, in future, be included in a standard care pathway.

Our ultimate goal is to develop a new fNIRS device that can be used in clinics around the world (EarGenie®).

2. Who is running the project?

This project is being run by the EarGenie team at the Bionics Institute, led by Professor Colette McKay. The clinical team is made up of qualified and experienced paediatric audiologists.

It is taking place at the Bionics Institute in East Melbourne, Victoria.

It is being funded by

- the National Health and Medical Research Council of Australia,
- the Australian Government through the Medical Research Future Fund,
- We may apply to government organisations, philanthropists, or investors for more funding for this project.

The Bionics Institute may benefit financially from this research project if, for example, the project assists them in the future to obtain regulatory approval for a new commercial device that performs the fNIRS tests. The following research team members hold patents relating to the methods used in the fNIRS hearing test: Colette McKay, Julia Wunderlich, Onn Wah Steven Lee, Darren Mao, Gautam Balasubramanian.

3. Why are we asking you to take part?

We are asking you to take part in this research project because you are a qualified audiologist who has at least 1 year of experience in paediatric diagnostic, hearing aid or cochlear implant audiology service provision in Australia.

4. What do you need to do this project?

If you take part in this project, you will need to look at a set of infant test results and complete an online questionnaire where you answer clinical questions and rate your confidence in the decisions you have made. For each infant there is one questionnaire which will take no more than 10 minutes to complete. The questionnaires will be given to you at various times throughout the study, i.e., as the infants are tested.

You may not receive test results for every infant in the study. When we have infant test results, we will randomly select a number of audiologists from the pool of independent audiologist participants. You may be one of them, provided that you are not currently involved in the infant's clinical care. If you are selected, you will be randomized to receive either the standard test results alone or the standard plus fNIRS test results. This means that sometimes you will be completing the questionnaire based on the standard test results alone and sometimes you will have the fNIRS test results as well.

You will be asked to complete up to about 2-3 questionnaires per month, and you can complete them at a time that suits you within the required time frame.

5. Can you withdraw from the project?

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why.

If you leave the project we will continue to use any questionnaire responses that we have already collected from you unless you tell us not to. Please only join this research project if you are happy with this approach.

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

You will not get any benefits from this project. However, there is a chance that the managing audiologists of infants participating in the project will be assisted by their having access to the additional information provided by the fNIRS test. We hope that the project will benefit children with hearing loss in the future. We also hope that paediatric audiologists will benefit from the additional evidence that the fNIRS test provides. They could benefit by the fNIRS test being adopted into standard care for babies with hearing loss.

7. What are the possible risks, side effects, and inconveniences?

You may spend around 10-15 minutes filling in the questionnaire for each infant's data we send you. To thank you for your time, we will offer you a $50 gift card at the completion of every 10 infants you evaluate.

8. How will we keep your information confidential?

We will collect and use personal about you for research purposes. In this project, we will store your electronic information securely on an internal computer server. We will keep paper copies of your information in a locked filing cabinet. Your electronic and paper information will be stored at the Bionics Institute.

These people may access your child's identifiable information:

- Research team involved with this project
- Bionics Institute Research Governance Office
- RCH Human Research Ethics Committee
- Therapeutic Goods Administration

We will not share your identifiable information with anyone else except as required by law.

Sharing information

To advance science, medicine and public health, we may share your **deidentified** data with any current and future funders, research projects, medical journals or data research repositories. Some of these organisations may be located overseas. **Any data that we send overseas is not protected by Australian laws and regulations.** By signing this consent form you are giving us permission to do this.

If we share your data, we will remove identifying details such as your name, years of practice and area of specialty and give the data a special code number. We will put security measures in place to prevent re-identification of your identity. These security measures include keeping the key to the special code number in a separate file that can only be accessed by the research team.

We will also put security measures in place to protect your data if and when we transfer it to other people. It will be transferred via secure connections in password protected files.

Despite our best efforts, there is a small chance that you could be re-identified by someone outside of this research project. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that you may have been re-identified, please let us know.

You have the right to access and correct the information we collect and store about your child. This is in line with relevant Australian and/or Victorian privacy and other relevant laws. Please contact us if you would like to access this information.

Storage of information

As this is a clinical trial involving babies, we will keep the project data for 25 years after the completion of the trial. The data will be securely stored at the Bionics Institute.

9. **How will you find out the project results?**

At the end of the project, we will send you a newsletter. This newsletter will explain what we found out in this project – in other words, our project results. The newsletter will not have any information specifically about you.

10. Who should you contact for more information?

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

Name:	Professor Colette McKay
Contact telephone:	03 9667 7500
Email:	cmckay@bionicsinstitute.org

For other urgent matters related to this project, please contact Professor Colette McKay on the details above.

You can contact the Director of Research Operations at The Royal Children's Hospital if you:

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

You can phone the Director on (03) 9345 5044 or email them at rch.ethics@rch.org.au.

Consent Form

Project Number: 90457

Short Name of Project: fNIRS to improve early intervention

Version Number: 3 **Version Date:** 13/4/2023

- I have read this information statement and I understand its contents.
- I understand what I have to do in this project.
- I understand the risks I could face because of my involvement in this project.
- I voluntarily consent 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.

Participant Name	Participant Signature	Date
Name of Witness to	Witness Signature	Date

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their 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.