

PARENT/GUARDIAN INFORMATION STATEMENT AND CONSENT FORM

HREC Project Number: 27053

Research Project Title: Genetics of Speech Disorders

Principal Researcher: Dr Angela Morgan, Senior Research Fellow

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.

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.

Your child is 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, they 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.

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 project about?

This project is looking at the genetic causes of speech disorder. Speech disorder disrupts the natural flow of communication. This can have an impact on self-esteem, school, work and general well-being. It is a common problem, with 5% of the population experiencing a speech disorder at some time in their lives.

Childhood speech disorder typically begins between two and five years of age. Many children will grow out of it, but others will go on to have a persistent speech disorder. Previous research into families and twins has shown that speech disorder often runs in families. This suggests that some families may inherit one or more genes, which make it more likely that they will have a speech disorder. In addition, other genes may be inherited which make it more likely that a person will recover, or a speech disorder will persist.

Genes are the instructions inside you that tell your body what to look like and how to work. Genes are arranged on chromosomes, and these chromosomes are inside almost every cell of your body. Each cell will have about 30,000 genes located on 46 chromosomes inside them. Genes get passed down in families from

parents to children. Because speech disorder can run in families, it is possible that speech disorder is caused by a change in a gene.

To date, only a small number of genes for childhood speech disorder without other neurological causes have been identified. We hope to discover other genes that are associated with speech disorder. We aim to use new genetic techniques to search for genes related to speech difficulty in families where there are a number of members with speech disorder, as well as in individuals where we think that the speech disorder may have a genetic basis (e.g., in severe and persistent speech disorder).

We hope that by working with families with a history of speech disorder, or individual children/adults who may have a genetic basis to their speech disorder, that the genetics of speech impairment will become clearer. By trying to identify gene changes associated with speech disorders, we will learn more about what causes someone to have speech problems, be able to identify people who are at high risk of speech disorder, and develop better treatments.

2. Who is funding this research project?

This project is funded by the Australian Research Council, National Health & Medical Research Council and small philanthropic grants from the Shepherd Foundation, ANZ Trustees, Perpetual Charitable Trustees and the Austin Hospital Medical Research Fund.

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

We are asking your child to take part in this project because they have a family history of speech disorder, or because they have a speech disorder.

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

We would like you and your child to see your local speech pathologist who will complete a speech and language assessment with you. The appointment may take up to 2 hours.

Your child will be asked to:

- Perform a series of assessments that determine their ability to understand and produce words, sounds and sentences as well as making different movements with their mouth, eg. poking out their tongue or pursing their lips.
- Perform a number of tasks that will test their cognitive ability.

The assessments may be audio and video-recorded. We would like to complete a questionnaire with you about your child's birth and development history, medical history and history of communication or speech problems. We would also like to obtain information from your child's speech therapy or medical records. The information we need includes if/when they were diagnosed with speech disorder, the type of speech disorder they have, details of any treatments they have had, and whether they have any other medical disorders. We may also get this information from your child's speech therapist if they are currently in therapy.

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

You and your child do not have to take part in this project if you do not want to.

If you take part and change your mind, you can stop at any time without telling us why. If you withdraw from the project we will use any information collected from your child unless you tell us not to.

6. What are the possible benefits for my child?

We cannot promise that your child will get any benefits from this project.

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

The real benefit from this project will come in the future. We hope we will be able to provide better information to parents about whether their child who has speech disorder is likely to have ongoing difficulties, or whether the problems are likely to be short-lived. This is important so that we can begin to find out some of the reasons that speech disorders occur and it may help us to work out who will benefit most from early intervention and treatment.

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

There are no known or foreseeable risks. Your child may become tired during testing, but we will offer plenty of breaks to avoid fatigue.

9. What are the possible inconveniences?

The only inconvenience is the time to come to the appointment.

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

Any information we collect for this research project that can identify your child will be treated as confidential. We can disclose the information only with your permission, except as required by law.

All information will be stored securely at the Murdoch Childrens Research Institute. Your child's information will also be stored on a password-protected computer database.

The following people may access information collected as part of this research project:

- the research team involved with this project
- The Royal Children's Hospital Human Research Ethics Committee

The information will be identifiable. This means that your child's name and/or other personal details will stay on the information.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about your child. Please contact us if you would like to access your child's information.

When we write or talk about the results of this project, information will be provided in such a way that your child cannot be identified. In some cases, we may ask to use a photograph or video-recording of your child in research presentations or scientific research articles.

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

We will send you a summary of the overall project results. The summary will be of the whole group of participants, not your child's individual results. We will send a summary report of your child's assessment results if requested.

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: Dr Angela Morgan

Contact telephone: +61 (3) 8341 6458

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.

CONSENT FORM

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Version Number: 8 **Version Date:** 17/10/2011

- I voluntarily consent for my child to take part in this research project.
- I believe I understand the purpose, extent and possible risks 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 this project has been approved by The Royal Children's Hospital Human Research Ethics Committee and will 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 Parent/Guardian Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to my child's photograph or video recording being used in scientific presentations or research articles
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Child's Name

Parent/Guardian Name

Parent/Guardian Signature

Date

Name of Witness to Parent/Guardian's
Signature

Witness Signature

Date

I have explained the project to the parent/guardian who has signed above, and 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.