EXPLORING BRAIN STRUCTURE AND FUNCTION OF YOUNG CHILDREN AT RISK FOR STUTTERING

PARENTAL INFORMATION STATEMENT

(1) **What is this study about?**

Your child is invited to take part in a research study investigating the brain structure and function of young children at risk for stuttering. Children at risk for stuttering and children not at risk for stuttering will be scanned using non-invasive magnetic resonance imaging (MRI). The findings of this study will contribute to understanding the cause of stuttering.

You are invited to give consent for your child to participate in this study because your child is:

- between 6 and 18 weeks of age
- at risk for stuttering due to the presence of a family history
- not at risk for stuttering due to no knowledge of a family history of stuttering.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to let your child take part in the research. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research study is voluntary. So it’s up to you whether you wish to let your child take part or not.

By giving your consent you are telling us that you:

- Understand what you have read
- Agree for your child to take part in the research study as outlined below
- Agree to the use of your child’s personal information as described.

You will be given a copy of this Parental Information Statement to keep.
(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Mark Onslow, Director, Australian Stuttering Research Centre, The University of Sydney
- Associate Professor Ann Packman, Senior Research Officer, Australian Stuttering Research Centre, The University of Sydney
- Associate Professor Ross Menzies, Australian Stuttering Research Centre, The University of Sydney
- Associate Professor Jim Lagopoulos, Brain and Mind Research Institute, The University of Sydney
- Dr Susan O’Brien, Research Program Coordinator, Australian Stuttering Research Centre, The University of Sydney
- Dr Robyn Lowe, Postdoctoral Research Associate, Australian Stuttering Research Centre, The University of Sydney
- Dr Martin Sommer, Consultant, Department of Clinician Neurophysiology, University of Goettingen, Germany

(3) What will the study involve?

This study involves scanning young children using magnetic resonance imaging (MRI) and diffusion tensor imaging.

- Your child’s eligibility to participate will be assessed during a phone call in which a researcher will ask you a series of questions relating to the presence of stuttering in your family.
- If eligible and you give consent for your child to participate, you will attend one session with your child at the Brain and Mind Research Institute, Camperdown for up to two hours.
- During this session, you will naturally interact with your child to feed and settle them.
- To comfortably secure your child during the scan, they will be wrapped in an MRI safe cradle for the procedure *(Med-Vac’s Air Right, Chambered Bag)*. This cradle prevents the baby from moving around during the procedure so that we can get a clear scan of the brain.
- To protect your child’s hearing, your child will be fitted with paediatric ear plugs and mini ear muffs for the duration of the scanning procedure.
- During natural sleep or when awake but settled, your child will be positioned in the MRI scanner.
- The scanning procedure will take up to 40 minutes to complete.
- During the scan, you can wait in the observation room near the MRI scanner.
- If at any time during the procedure your child becomes unsettled and you feel that your child is too distressed for the scan to continue, the procedure will be discontinued by the radiographer and your child will be brought to you for comforting.
- If you choose, and as long as time permits, the scan may be reattempted after resettling your baby.
- If your child is unable to be settled initially, the procedure will not be attempted. If you choose, you may reschedule another visit.
- When your child is five years of age, we will contact you again to conduct an interview to determine if your child ever stuttered.

(4) How much time will the study take?

Your involvement in this study will take up to 2 hours. Time will be allowed to settle your child with your usual routine, for example, following feeding. The scanning procedure will take from 20-40 minutes to complete.
(5) Who can take part in the study?

Children eligible to participate include:
- Infants aged between 6 and 18 weeks of age
- Infants with a family history of stuttering
- Infants without a family history of stuttering

A family history of stuttering will be determined by confirmation that 2 immediate family members stutter or have a history of stuttering.

Children ineligible to participate include:
- Infants diagnosed with a congenital birth condition, for example, Downs Syndrome.

(6) Does my child have to be in the study? Can they withdraw from the study once they’ve started?

Being in this study is completely voluntary and your child does not have to take part. Your decision whether to let him/her participate will not affect your/their relationship with the researchers or anyone else at the University of Sydney now or in the future.

If you decide to let your child take part in the study and then change your mind later, you are free to withdraw your child from the study at any time.

If you withdraw your child from the study, we will not collect any more information from him/her. Please let us know at the time of withdrawal what you would like us to do with the information we have collected up to that point. If you wish, their information will be removed from our study records and will not be included in any future publications.

(7) Are there any risks or costs associated with being in the study?

Magnetic resonance imaging (MRI) is a non-invasive scanning procedure that does not involve any radiation. Your child will not be sedated during the procedure but will be scanned whilst safely and supportively wrapped in a purpose-designed cradle.

Possible risks may include:
- Distress for your child from the scanning noise. Your child will be fitted with paediatric ear plugs and mini ear muffs to reduce this noise.
- Distress for your child as a result of waking during the procedure. The procedure will be discontinued by the radiographer at your request if you believe your child is becoming too distressed to continue.
- Distress for you if your child wakes during the procedure and starts to cry. Your child may be crying or show signs of having cried when returned to you.
- Psychological distress for you due to the possibility that the scans may alert you to a diagnosis of a previously unknown condition.

If abnormalities in your child’s scans are detected as part of this study, the Neuroradiologist will inform you and prepare a medical report. In some cases additional formal clinical scans may be required (as determined by the Neuroradiologist). If this is the case the additional clinical imaging will be provided free of charge and a referral to a Neurologist and/or Neurosurgeon can be arranged without delay. It should be emphasized that these occurrences are rare.
(8) **Are there any benefits associated with being in the study?**

We cannot guarantee or promise that your child will receive any direct benefits from being in the study.

(9) **What will happen to information that is collected during the study?**

By providing your consent, you are agreeing to us collecting personal information about your child and your family for the purposes of this research study. Their personal information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

The data collected from the MRI scans will be analysed only by the researchers involved in this study.

Your child’s information will be stored securely and his/her identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but neither you nor your child will be individually identifiable in these publications. Only the researchers involved in this study will have access to the data during this time.

We will keep the information we collect for this study, and we may use it in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

(10) **Can I or my child tell other people about the study?**

Yes, you are welcome to tell other people about the study.

(11) **What if we would like further information about the study?**

When you have read this information, Dr Robyn Lowe will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Dr Robyn Lowe, by email: robyn.lowe@sydney.edu.au or phone: 02 9351 9061.

(12) **Will we be told the results of the study?**

You have a right to receive feedback about the overall results of this study. This feedback will be in the form of a one-page summary posted on the web-site of the Australian Stuttering Research Centre, the University of Sydney. You can also nominate other means of receiving feedback on the results of this study by ticking the relevant box on the consent form. This feedback will be available after the study is finished.

(13) **What if we have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project no. 2014/386]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.
The Manager, Ethics Administration, University of Sydney:
- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

*This information sheet is for you to keep*