

Project Title	PREBO-6: <u>P</u>rediction of childhood <u>B</u>rain <u>O</u>utcomes in infants born preterm using neonatal MRI and concurrent clinical biomarkers		
HREC Number	HREC/19/QCHQ/49800		
Investigators	Dr Joanne George, Dr Alex Pagnozzi, A/Prof Samudragupta Bora, Prof Roslyn Boyd, Prof Paul Colditz, Prof Stephen Rose, Prof Robert Ware, Dr Kerstin Pannek, Dr Jane Bursle, A/Prof Karen Barlow and Dr Kartik Iyer		
Version Number:	2.0	Version Date:	12 February 2019

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to ask your child to participate in a research project that is explained below.

It is ok to say no

What is an Information Statement?

These pages tell you about our research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement 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.

Important things to know

- It is your choice whether or not your child can take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child receives through Children's Health Queensland

If you would like your child to take part in the research project, please sign the consent form provided by the Researcher. By signing the consent 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 information and consent form to keep.

1. What is the research project about?

Thank you for your child's participation in the PPREMO or PREBO study when they were a newborn baby. This study was designed to understand very early brain development in children who were born prematurely, and to look for ways to identify which children might need additional help with movement and learning. As you will remember, your child had MRI scans (brain scans) and assessments of their movements shortly after birth and again when they reached term age. The early part of the study followed up children at 1 and 2 years of corrected age.

We are now extending the project to offer assessment at **6 years corrected age**. We are doing this to learn if our early MRI scans or the clinical assessments can predict a child's outcomes in early childhood. If this is found to be the case, then in the future, families will be provided with information on their child's likely development much earlier. This will enable families to receive support and their children to be offered earlier treatments to help them with their movement, learning or behavioural development.

2. Who is funding the research project?

The National Health and Medical Research Council of Australia (1161998)

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

All families of children who participated in the original PPREMO and PREBO studies are being contacted to ask if they would like to participate in this follow up study.

4. What does the study involve?

There are three parts to this study which will be offered over 2 days:

- a. Movement, learning and language assessments (including parent questionnaires)
- b. EEG (recording brain activity)
- c. MRI (brain scan)

a. Movement, learning and language assessments:

A range of movement, learning and language assessments will be completed by suitable healthcare professionals (e.g., research psychologist, physiotherapist, nursing) or advanced trainees under full supervision. The assessments can take up to 4.5 hours with breaks to ensure your child does not get too tired. Some of these assessments will involve direct participation of your child through a series of play-based (solving puzzles, memory games) and/or school activities (reading etc.). For other assessments, parents will be asked to complete questionnaires in relation to their child's development and behavior. Assessments will be videoed for quality assurance and scoring purposes. Please let us know if you do not want to be video recorded.

b. Electroencephalography (EEG)

This is a recording of the electrical activity of your child's brain (brain waves). It involves placing a cap on your child's head that contains a number of small, soft sponges. This does not hurt your child and there is no potential for harm. Brain waves are recorded to a computer for approximately 15 minutes. Your child will sit quietly in a comfortable chair and watch a movie. The whole procedure, including putting the cap on and taking it off, will take approximately ½ an hour.

c. Magnetic Resonance Image Scan (MRI) of your brain

The MRI will include taking pictures of your child's brain while he/she is resting on their back, and then while he/she is moving his/her hand. MRI is safe. There is no ionizing radiation and it has no

known dangerous or harmful effects. It is painless and your child will be awake as no sedation or any other drugs are given.

We will ask your child to lie on a table inside the MRI scanner. Some people feel uncomfortable in the MRI scanner because of the tight space. To help make your child feel comfortable he/she will be offered to watch an age-appropriate movie and to undertake some preparation to be familiar with the MRI and tasks we will ask them to do. Your child can withdraw from the MRI scan at any time, before and also during the scan. A member of our team can stay with your child at all times. We are also in constant communication with your child via a two-way intercom system. The test should take approximately 1-1.5 hours to complete, but only 30-45 minutes of this time will be spent inside the scanner.

The scanner will record information about your child's brain. It is very important that your child keeps very still during the scanning. When your child lies on the table we will make sure that they are in a comfortable position so that they can keep still. The scanner can be noisy and we will give your child some special earphones to reduce the noise. During the MRI scan we will ask your child to do some movement tasks with their hand. It is very important that they lie completely still.

5. What if I wish to withdraw from the research project?

My decision whether or not my child participates will not negatively affect or impact their future relations with Children's Health Queensland. If I decide for my child to participate, I am free to withdraw my consent and to discontinue participation at any time. The decision to withdraw my child from the study will not affect their routine medical treatment or their relationship with the people treating them.

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

Families will receive a free, comprehensive, and specialized assessment of their child's development and will be provided with a report. This type of assessment is not performed as part of routine healthcare or neurodevelopmental follow-up. If any significant developmental concerns are identified during the course of the study then, with your permission, this report can be made available to your Paediatrician /GP or specialist (with your consent), whom may then refer you for treatment if they believe necessary. Therefore, a possible benefit of study participation will be the timely identification of any neurodevelopmental difficulties and subsequent referral to appropriate services, which may have otherwise gone unnoticed. Early identification and appropriate intervention will likely lead to improved developmental outcomes that may assist in reaching the child's fullest potential.

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

This is an observational cohort study with no known health or safety risks to participants. The assessments will happen at the Centre for Children's Health Research (CCHR) in South Brisbane on day 1 for the clinical assessments and EEG. The following day the MRI scan will be conducted at the Herston Imaging Research Facility in the Royal Brisbane and Women's Hospital precinct. These appointments will be planned to minimize any inconvenience to you. The only anticipated burden to the participants and their accompanying family members will be to visit CCHR, South Brisbane, for a few hours so that age-appropriate assessments can be performed on day 1 and then to visit the Royal Brisbane and Women's Hospital for the MRI scan on day 2. We anticipate these assessment visits to last for 5 hours on day 1 and 2 hours on day 2. Free parking will be provided at both sites. Support for travel and accommodation will be offered to families travelling from regional and rural Queensland, interstate, or New Zealand.

MRI scans:

The noise during an MRI can be loud but we use high-quality headphones to reduce the noise to safe levels. Keeping still during the MRI is important, so we will use velcro strapping to keep your child's head and body still - this can be a little uncomfortable after 30-45 minutes of scanning. We will provide video and other information before your child's MRI appointment. On the day of the assessment, researchers will go through a power point presentation with your child and he/she will be able to ask questions regarding MRI. Our research team is very experienced at supporting children having MRI.

If you/your family would prefer not to participate in the MRI at any stage of the project, you will be able to remain in the study and complete the other clinical assessments without the MRI component.

The scans taken are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at the MRI scans for features relevant to the research project. On rare occasions, the specialist may discover an unexpected finding that could have a significant risk to a participant's health. If this happens, we will contact participants and their families to talk about the findings. In the unlikely event that an unexpected finding is discovered, it could have consequences for a participant. It may affect their ability to work in certain professions, or get life or health insurance. However, if we do find an unexpected feature, a participant may be able to get treatment that might be of benefit. We cannot guarantee that we will find any/all unusual features. Participants (or in this case the child's Parent/ Caregiver) will be notified of these issues when they are considering being in the study.

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

All results of assessments/questionnaires will be stored with your child's study number and not their name on them. This number is used to identify the assessments and is linked to your child's name but the linking file will be kept confidential and only made available to the researchers. We will use electronic forms and all information will be kept on a database at the Queensland Cerebral Palsy and Rehabilitation Research Centre, South Brisbane Queensland. Any paper forms that we use to record the assessments and questionnaires will be stored in a secure filing cabinet and only the researchers will have access to this information. The paper forms containing assessment or questionnaire results will be kept at the Queensland Cerebral Palsy and Rehabilitation Research Centre in Brisbane in a locked filing cabinet. Videos of the assessments will be kept at the Queensland Cerebral Palsy and Rehabilitation Centre on a secure University of Queensland server. Records including recordings will be retained in accordance with the obligations under the Public Records Act 2002 and associated State policies, retention and disposal schedules and other official advice issued by the Queensland State Archives' State Archivist <https://www.qld.gov.au/dsiti/qsqa>. If we give talks or write about the results of this project, we will not use any names or identifying details.

9. Sharing data between studies:

If you have consented to other studies where there is a common assessment or video we ask your consent to share this data.

10. Who should I contact for more information?

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 Joanne George
Contact telephone: 07 3069 7371
Email: j.george2@uq.edu.au

HREC Information:

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the HREC Co-ordinator on: 3069 7002 or email CHQETHICS@health.qld.gov.au

Local Governance Contact Information:

Name: Dr Peng Tjun Choy
Contact telephone: 07 3069 7008
Email: CHQ_RGO@health.qld.gov.au

**CHILDREN'S HEALTH QUEENSLAND
PARENT/GUARDIAN CONSENT FORM**



Title PREBO-6: Prediction of childhood Brain Outcomes in infants born preterm using neonatal MRI and concurrent clinical biomarkers

Project Number HREC/19/QCHQ/49800

Principal Investigator Dr Joanne George

Declaration by Parent/Guardian

I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

Please tick

I consent for my child to be video and audio recorded for the purpose of collecting the data and scoring the assessments Yes No

I consent for my child to receive the Brain MRI scan Yes No

I agree to be contacted in future if a further research study is planned Yes No

I would like a copy of the report to be provided to my child's treating clinician (e.g. GP, paediatrician etc.) Yes No

If yes, please provide name and contact details:

Name of Child (please print)	_____
Name of Parent/Guardian (please print)	_____
Signature of Parent/Guardian	_____ Date _____

Declaration by Study Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study Researcher (please print)	_____
Signature	_____ Date _____