Parent Information and Consent Form (PICF)

Title of the Research study: Prediction of PREterm Motor Outcomes (PPREMO)

Thank you for taking the time to read the information in this form. These pages contain information about a research project we are inviting you and your baby to take part in. The purpose of this information is to explain to you clearly and openly all the steps and procedures of this project. The information is to help you to decide whether or not you would like to take part in the study. Please read this information carefully. You can ask us questions if you wish. You may also wish to talk about the project with others e.g. friends or a health care worker. When you understand what the project is about, you can sign the consent form attached if you agree to take part. You will be given a copy of this PICF to keep.

What is the Research Project about?
This project is for babies born before 30 weeks gestation (preterm). Some babies who are born preterm can have problems later in life (for example with learning, movement or behavior). It is difficult to know which babies will have problems and which babies won't. This makes it difficult for doctors to know which babies will need extra help with their development of learning and movement skills.

Magnetic Resonance Imaging (MRI) scans of your baby's brain can be performed safely at an earlier stage (30 weeks) than has been possible in the past (at term). MRI's are safe and provide information about your baby's brain and how it compares to babies born at term. Early brain scans are one of the tests we will be investigating in this study.

The **purpose** of this research project is to learn which tests (clinical and MRI) can be used at 30 weeks and 40 weeks, to accurately identify which babies may have problems later in life, so that those babies and their families can be provided with the help they need as early as possible.

Why are you being invited to be in the study?
We are inviting all parents/guardians of babies born at less than 30 weeks in this hospital to participate in the study. We will also invite some babies born at term to serve as a comparison group.

What are your alternatives to participating in this project?
There is no obligation to participate in this study. Should you choose not to participate in this project you and your baby will have all the usual access to treatment. What does this study involve?

There are 4 stages of this study:

1. At **30 weeks of age**, while your baby is still in the nursery we will carry out the following:
   - clinical and medical information will be collected from the baby's chart
   - Video of their movements in their incubator or cot (up to 1 hour of video; no handling of the baby)
   - A neurological/neurobehavioural assessment (15-20 minutes; involves a small amount of handling)
   - A brain scan (MRI) which takes about an hour (20 minutes preparation and 40 minutes in the scanner)

2. At **40 weeks** which is term equivalent age; if you have returned home we will ask you to visit the hospital. We will complete:
   - A video of their movements for a short period (up to 15 minutes)
   - Movement assessments and a neurological assessment (30-40 minutes)
   - Assessment of their visual functions (5 minutes)
   - A brain scan (MRI) which takes up to one hour (20 minutes preparation and 40 minutes in the scanner)
   - A recording of their brain's electrical activity (EEG; 30 minutes preparation and 30 minutes recording).
   - Ask you to complete a brief questionnaire of social and environmental factors that relate to your family

3. At **12 weeks corrected age** (3 months after term); we will visit you at home and:
   - Video your baby's movements for a short period (5-15 minutes)
   - Perform a movement assessment (40 minutes)
   - Assess their visual function (5 minutes)

4. At **12 months corrected age;** we will ask you to visit the hospital:
   - A paediatrician will assess your baby's general development (30 minutes)
   - We will perform movement assessments (11/2 hours)

What is an MRI and what does it involve?

A magnetic resonance scan (MRI) involves your baby being transported by a doctor and a nurse from the nursery to the MRI facility on the 3rd floor of the Royal Brisbane and Women's hospital in a special incubator that allows similar monitoring to that in the nursery. MRI is safe, there is no radiation, it has no known dangerous or harmful effects, causes no pain, and no sedation or any drugs are given to your baby.

The MRI will be performed in the same way as for all babies who require MRI in the hospital. You will be provided with an MRI Fact Sheet that is made available to parents of all babies having an MRI in the hospital. The scanner will take pictures of your infant's brain using magnetic and radio waves. No medications or X-rays are used, there is no radiation involved and there is no potential for harm. Before the scan your baby will be fed in the usual way to encourage him/her to sleep during the scan. He/she will then be positioned in a comfortable pillow in the scanner and monitored over the scan time (approximately 40 minutes). During the scan most infants sleep as it is after a feed.

Ear muffs will be placed over their ears as part of the MRI scan is noisy. A sensor will be placed on the hand or foot to monitor heart rate and oxygen levels as a safety measure,

because during the MRI the baby is not clearly visible. A doctor and a nurse from the Neonatal Nursery will be with the baby at all times to monitor the baby and the Hospital has an established emergency protocol to follow in the unlikely event that vomiting or apnoea (stopping breathing) occurs. MRI does not increase the risk of these events which can happen to any baby at any time.

What is an EEG and what does it involve?
EEG is a standard method to measure brain waves in babies. It involves cleaning the skin on the head and applying some stick on electrodes. This does not hurt your baby and there is no potential for harm. Brain waves are recorded to a computer. The recording, which lasts for up to about 30 minutes can be made regardless of whether your baby is asleep or awake.

What is the Neonatal assessment of visual functions?
When your baby is alert, we will test how your baby looks at (fixes and follows) a series of cards designed to test their vision.

What is the Questionnaire I will be asked to complete?
Any child's development is influenced by both medical or biological factors (such as prematurity, illness etc.) and social or environmental factors (such as the home environment). The information you provide in the questionnaire is totally confidential, and will allow us to understand which information from our assessments is as a result of their prematurity. We are only investigating the biological or medical factors relating to prematurity.

Who are the Researchers?
Joanne George, a physiotherapist, and Dr Raymond Chuk, a doctor, lead the project and will perform all assessments on your baby. Other researchers involved in this project include: Professor Paul Colditz (a neonatologist and Professor of Perinatal medicine), Professor Roslyn Boyd (a physiotherapist), Associate Professor Stephen Rose and Kerstin Pannek (physicists' who will analyze your baby's MRI scan), Professor Alan Coulthard (a radiologist), Sonia Sam and Rebecca Caesar (physiotherapists who will also perform some motor assessments), Dr Barbara Lingwood (a scientist who may analyze some of the data), Karen Taylor (a nurse who will explain the study to you), and Dr Robert Ware (a biostatistician who will analyze some of the data).

What are the benefits of participating in this study?
Additional assessments will be performed, compared to babies not in the study. The information from these assessments will be provided to your child's doctor who will pass the information on to you in your regular appointments. You will have the opportunity to gain a set of MRI scan films of your infant's brain for the future record of your child. If any neurodevelopmental issues arise when your child is older, the MRI scans may be helpful. You will have the opportunity to discuss your child's progress in depth and discuss any concerns with experienced staff. You will have an opportunity for in depth neurodevelopmental assessments at 40 weeks (term), as well as at 12 weeks post term and 12 months of age.

Is there likely to be a benefit to other babies in the future?
If MRI and/or movement assessments performed at 30 weeks and 40 weeks are shown to be accurate in terms of predicting movement development at 1 year of age, then this finding will benefit many babies in the future. If future practice is made better, this may benefit other premature babies in the future.

What are the possible risks and/or side effects for my baby?
There are no anticipated risks to your baby as a result of being part of this research project. However if any risks become evident at any time, we will let you know immediately.

There are no known risks of Magnetic Resonance Imaging. MRI is commonly done for research purposes for infants born preterm. Most infants will sleep or rest during the scan. If your baby becomes distressed for any reason the study will be stopped. Your baby will be monitored carefully throughout the scan by trained medical and/or nursing staff.

There is the possibility that the MRI scan will show up something in your infant's brain that we had not expected. If this happens, we will arrange for you to meet with a medical professional who can explain the findings to you. If any of the results of the MRI, or neurodevelopmental assessments, are distressing for you we will arrange specific counseling to discuss the findings with specially trained staff. Although detecting a significant brain abnormality is extremely unlikely, you should be aware that if an abnormality is detected in your child and you are told about it, then this knowledge may have consequences for your child. Knowing about an abnormality may affect their ability to work in certain professions, obtain life or health insurance and other facets of daily living, however you should be aware that this is unlikely. Please take the time to consider carefully what it would mean if we told you your child had an abnormality in their brain that might, or might not, affect your child in later life. If you do not wish to know this, then you may wish to discuss this further before agreeing to participate. You can choose to participate in the study but not receive information from the scans and movement assessments.

What are the possible discomforts and/or inconveniences for my baby or me?
The inconvenience to you and your baby is the time that the assessments will take, and the trips you will need to make to the hospital. Families will have to make between 1 and 2 trips to the hospital for the assessments. We will make the appointments at a time that suits you and provide some compensation for travel costs and parking.

The MRI scanner is noisy, so protective earmuffs will be positioned over your infant's ears during the scan.

What will be done to make sure the information is confidential?
All results of all assessments will be stored without your child's name on it. All hard copy data will be stored in a secure filing cabinet and only the researchers will have access to these. If we talk or write about the results of this research, we will not use any names. All data is only accessible to the study personnel.

Queensland Health guidelines require the storage of research data involving minors to be kept for 15 years after the child has turned 18 years of age.

As is regular procedure in infant studies, the name of the family GP will be collected in order to allow direct sharing of information and concerns regarding potential risks for the child if necessary.

Will I be informed of the results when the research project is finished?
A regular 6 monthly newsletter will also be sent to you to keep you updated on study recruitment and progress. At the conclusion of the study all families will be sent a meaningful summary of the overall study results, and copies of publications if requested

Participation in future research
In the consent form we will ask you if you agree to be contacted in the future if further follow up studies are developed. Your consent to be contacted would only apply to extended research which relates to the current research project. Full ethical approval would be sought by the research team and a new consent process undertaken. You can choose to participate in this study but decline to be contacted for future research.

Participation in this study is voluntary
You can decide whether or not you wish to take part in this research project. You can decide to withdraw from this research project at any time. No explanation is needed. You may like to discuss your participation in this research project with your family and/or with your doctor. You can ask for further information before deciding if your child will take part.

If you would like more information about the study or if you need to contact a study representative in an emergency, the person to contact is:

Professor Paul Colditz,

Royal Brisbane and Women's Hospital

Contact telephone: (07) 3346 6014

This study has been reviewed and approved by the Royal Brisbane & Women's Hospital, Human Research Ethics Committee (HREC). Should you wish to discuss the study in relation to your rights as a participant or should you wish to make a independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld 4029 or telephone (07) 3636 5490, email Ethics@health.qld.gov.au

STANDARD INFORMED CONSENT
FOR PARENTS / GUARDIANS TO GIVE CONSENT
FOR THEIR BABY TO PARTICIPATE IN A RESEARCH PROJECT

Title of Project

Prediction of Preterm Early Motor Outcomes (PPREMO)

Principal and associate Investigators	Professor Paul Colditz, Professor Roslyn Boyd, Joanne George, Dr Raymond Chuk, Sonia Sam, A/Prof Stephen Rose, Kerstin Pannek, Professor Alan Coulthard, Rebecca Caesar, Karen Taylor, Dr Barbara Lingwood, Dr Robert Ware

I/We (Parents/Guardians name) _____

Parents/Guardians of (baby's name) _____

voluntarily consent to him / her taking part in the above titled Research Project, explained to me by

Mr / Ms / Dr / Professor

- I/We have received a Participant Information and Consent Form (PICF) to keep and I/we understand the purpose, extent and possible effects of my baby's involvement
- I/We have been asked if I/we would like to have a family member or friend with me/us while the project is explained
- I/We have had the opportunity to ask questions and I/we am/are satisfied with the answers I/we have received/We understand that the researcher has agreed not to reveal results of any information involving my/our baby, subject to legal requirements
- I/We understand that the name of our family GP will be collected in order to allow direct sharing of information and concerns regarding potential risks for the child if necessary.
- If information about this project is published or presented in any public form, I/we understand that the researcher will not reveal my/our baby's identity.
- I/We understand that if I/we refuse to consent, or if I/we withdraw my/our baby from the study at any time with or without explanation, this will not affect my/our baby's access to the standard treatment that all babies receive.
- I/We agree to be contacted in future if a further research study is planned. Yes ☐ No ☐
- I/We understand I/we will receive a copy of this consent form.

	Printed Name	Signature	Date
PARENT/GUARDIAN 1			
PARENT/GUARDIAN 2			

I have explained the study to the parents/guardians who has signed above, and believe that they understand the purpose, extent and possible effects of their involvement in this study.

Printed Name _____ Signature _____ Date _____

RESEARCHER _____ _____

Note: All parties signing the Consent Form must date their own signature.