Parent/Guardian Information and Consent Form (Infant PICF)

It is ok to say no

Title	**Early Prediction of Infant Neurodevelopmental Outcomes**
Short Title	**ePINO**
Protocol Number	HREC/2022/QCHQ/85661
Project Sponsor	**The University of Queensland**
Coordinating Principal Investigator / Principal Investigator ***(to be added at each separate site)***	**Prof Roslyn Boyd**
Location ***(to be added at each separate site)***	**Queensland Cerebral Palsy and Rehabilitation Research Centre (QCPRRC)** **Child Health Research Centre, Brisbane**

Part 1 What does participation involve?

1 Introduction

This is an invitation for your baby to take part in this research project: "Early Prediction of Infant Neurodevelopmental Outcomes", because your baby was admitted to hospital soon after birth due to early or moderate to late preterm birth or because they were small at birth or had an early brain injury. We will also be asking some healthy babies born at term to serve as a comparison group.

This research project is aiming to help doctors to know which babies will quickly need extra help with their development of learning and movement skills.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want your baby and yourself to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether you and your baby will take part, you might want to talk about it with a relative, friend or your nurse or doctor.

Participation in this research is voluntary. If you do not wish for you and your baby to take part, you do not have to. You and your baby will receive the best possible care whether you decide to take part or not.

If you decide you and your baby will take part in the research project, you will be asked to sign the consent section. In some cases the signature may be given electronically. By signing the consent form you are telling us that you:
• Understand what you have read
• Consent to your baby taking part in the research project
• Consent to your baby having the tests and research that are described
• Consent to the use of your baby's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the Research Project about?

Some babies who are admitted to hospital soon after birth can have problems later in life (for example with learning, movement, or behaviour). 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.

The **ePINO** researchers hope to increase the understanding of how learning, movement and behaviour developmental problems occur so that they can improve early diagnosis and treatment strategies.

To do this the research will obtain information using a group of tests:
A. Clinical Assessments,
B. MRI (Magnetic Resonance Imaging) of your baby's brain,
C. EEG,
D. Genomics (genetic make-up) and Gut Microbiome

Using the group of tests **A, B, C & D** as early as possible the research project hopes to be able to accurately identify which babies may have problems later in life so that those babies and their families can be quickly provided with the help they need.

Do we have to take part in research?

No, all participation in research is voluntary. It is OK to say No. It is OK if at first you say yes and then decide No. If you do not wish to take part, or wish to change your mind about being involved, you may do so at any time.

When you are approached about this research study please feel free to ask as many questions as you need, to be able to understand the project and whether or not it would be right for you and your baby.

If you would like to be part of the study one of our researchers will meet with you to give you more information and answer any questions you may have. Once you have had a chance to talk things through with the researcher, and if you are still happy for you and your baby to take part, they will ask you to sign a consent form. Signing the consent document means that you are agreeing for you and your baby to take part in the trial and have understood what that will involve.

How do we know the research is safe?

The ePINO research project has been assessed, qualified, reviewed and approved by the Hospital's and University's Research and Ethics Committees to ensure that it is safe, relevant and important. The University and Hospital ePINO research team do not anticipate any 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

What would you and your baby have to do if I take part in the ePINO study?

You will need to provide your consent for ePINO's group of Tests -A, B, C, D

A. Clinical Assessments

Neurological assessments

These assessments look at how your baby is developing their skills of movement and posture, and how they are interacting with and responding to their environment. The researcher will move your baby's arms and legs, test their reflexes, place them in different positions such as on their tummy

and back and observe their movements, and to check your babies responses to sounds (such as shaking a rattle or bell) and observing how they respond. These assessments are video recorded for scoring purposes.

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

Questionnaires 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 assessments could be a result of your baby's high-risk status (i.e. born early, small, with a early brain injury).

Your baby's Feeding status will be checked at each study assessment you will be asked questions about whether your baby drinks breastmilk or formula, and the method you use to feed them (i.e., if they need tube feeding).

B. MRI

What is a brain MRI and what does it involve?
A magnetic resonance scan (MRI) of your baby's brain involves your baby being transported by a doctor and a nurse from the nursery to the MRI facility 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 as a safety check 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 medication or X-rays are used, there is no radiation involved and there is no potential for harm. No general anesthetic will be used.

Before the scan you baby will be fed in the usual way to encourage him/her to sleep during the scan. If your baby does not settle adequately the MRI will not be performed. 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.

Earmuffs will be placed over their ears during the MRI scan as it can be 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.

C. EEG

What is an EEG and what does it involve?

EEG is a standard method to measure brain waves in babies. It involves placing a cap on your baby's head that contains a number of small sponges. This does not hurt your baby and there is no potential for harm.

Your baby's natural 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.

D. Genomics and Gut Microbiome

The ePINO CP researchers hope to use an increased knowledge of the genetics and biology obtained from your baby's blood and other samples to find new, more effective treatments for various forms of disease, better predict the disease risk, to increase our understanding of how adverse neurodevelopmental outcomes such as Cerebral Palsy occur, and to enable improved accuracy of diagnosis and treatment strategies.

A separate Information Sheet and Consent Form explaining Genetics is being provided so that you can consider this part of the ePINO study.

Consent for Health Economic Evaluation

The economic analysis will include an estimate of all health care costs, including medical and pharmaceutical services utilized by your baby. You will be asked to sign a consent form authorising the study to access your baby's complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) from your baby's date of birth to the date of the assessment to evaluate your baby's medical and pharmaceutical cost as outlined in the consent form. Medicare collects information on your baby's doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies.

Services Australia is not involved in the conduct of this study other than to release your baby's Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information.

Services Australia will not provide your baby's personal information to the study without your consent. To participate in the study you must complete the 'Services Australia Participant Consent Form'.

The consent form is sent securely to Services Australia who holds MBS and PBS data confidentially.

What does this study involve?

You and your baby will be part of the study for around 24 months:

1. At **30-32 weeks of age (if your baby is in the preterm group)**, while your baby is still in the nursery, we will carry out the following:
   - Clinical and medical information will be collected from your baby's chart
   - A video of your baby's movements in their incubator or cot (up to 1 hour of video; no handling of your baby)
   - A neurological assessment (10-15 minutes; involves a small amount of handling). This assessment is videoed for scoring purposes.
   - A brain scan (MRI) which takes about an hour (20 minutes preparation and 40 minutes in the scanner)

- A recording of your baby's brain electrical activity (EEG; 30 minutes preparation and 30 minutes recording).

2. At **40-42 weeks of age** (term equivalent); if you have returned home, we will ask you to visit the hospital. We will complete:
   - A video of your baby's movements for a short period (up to 15 minutes)
   - Movement assessments and a neurological assessment (30-40 minutes). This assessment is videoed for scoring purposes
   - Assessment of your baby's 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 your baby's brain electrical activity (EEG; 30 minutes preparation and 30 minutes recording).
3. At **3 months of age,** we will visit you at home or invite you to return to the research centre to:
   - Video your baby's movements for a short period (5-15 minutes)
   - Perform a movement assessment (40 minutes). This assessment is videoed for scoring purposes.
   - Assessment of your baby's visual functions (5 minutes).
4. At **24 months of age,** we will ask you to visit the hospital for:
   - A paediatrician to assess your baby's general development (30 minutes)
   - To perform movement, cognition and growth assessments (1.5 hours). These assessments are videoed for scoring purposes.
   - You will be asked to complete some questionnaires about baby's feeding, diet, behaviour, quality of life and problem solving ability (executive function).

Who are the Researchers?

Professor Roslyn Boyd (a physiotherapist and Professor of Cerebral Palsy research leads the overall project), Professor Paul Colditz (a neonatologist and Professor of Perinatal Medicine) co-leads the project at the Royal Brisbane Women's Hospital.

Other researchers involved in this project include: Prof Rod Hunt (a neonatologist and Professor of Perinatal Medicine), A/Professor Atul Malhotra (Consultant Neonatal Paediatrician), Professor Michael Ditchfield (Paediatric Radiologist), Prof Michael Fahey (Paediatric Neurologist) at Monash Childrens Hopsital. Professor Stephen Rose, Dr Jurgen Fripp and Dr Kerstin Pannek (Physicists') at CSIRO, A/Prof James Roberts (an EEG specialist), A/Prof Severine Navaro (an expert on the Gut Microbiome) and Prof Nadia Badawi (a neonatologist) at Sydney Children's Hospital at Westmead.

This study is a multi-site study, to be carried out at the Royal Brisbane and Women's Hospital, Monash Children's Hospital and Sydney Children's Hospital at Westmead.

What are the benefits of participating in this study?

Benefits of this study include the additional assessments that will be performed, compared to babies not in the study. The information from these assessments will be provided to your baby's doctor who will pass the information on to you in your regular appointments. If any neurodevelopmental issues arise when your baby is older, the MRI scans may be helpful. You will have the opportunity to discuss your baby'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 3 months and 24 months of age.

Is there likely to be a benefit to other babies in the future?

If assessments performed at 30 weeks and 40 weeks are shown to be accurate in terms of predicting adverse development at 3 months and or 24 months of age, then this finding will benefit babies in the future. If future practice is made better, this may benefit other 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. Brain MRI is commonly done for research and clinical purposes for infants born early, small, or with the risk of a brain injury. 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. It 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. 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 baby'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. Video will only be viewed by study personnel for the purposes of data collection and assessment scoring.
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. This is a multi-site study so data will be sent among the research team between Victoria and Queensland. Your baby's data will be kept without your baby's name on it. Queensland Health guidelines require the storage of research data involving minors to be kept for 10 years after the baby 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 baby if necessary.
MRI recordings will be shared with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) researchers and the ePINO Research Team Members. CSIRO adheres to strict privacy policies that can be found at https://www.csiro.au/en/about/policies/privacy

Will I be informed of the results when the research project is finished?
The research will be published in scientific journals and copies of publications will be made available if requested.

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:

Royal Brisbane and Women's Hospital	Professor Paul Colditz, Contact telephone: (07) 3346 6014 Contact email: p.colditz@uq.edu.au
University of Queensland	Professor Roslyn Boyd

	Contact telephone: +61 0434608443 Contact email: r.boyd@uq.edu.au;	

This study has been reviewed and approved by the QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC). Should you wish to discuss the study with someone not directly involved, for matters concerning policies, information about the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Co-ordinator of the Ethics Committee on ((07)3069 7002 or email CHQETHICS@health.qld.gov.au

Local Governance Contact Information:

Name:
Phone:
Email:

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Queensland Government

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

Title of Project: ePINO Early Prediction of Infant Neurodevelopmental Outcomes

Principal Investigators	Prof Roslyn Boyd, University of Queensland; Prof Iona Novak, University of Sydney, Cerebral Palsy Alliance; Prof Stephen Rose , UQCCR, The University of Queensland and Advance Cell PLC ; Prof Michael Fahey, Monash Medical Centre and Monash University; Prof Paul Colditz, The University of Queensland; Prof Rod Hunt, Monash University, Monash Medical Centre; Prof Nadia Badawi, Westmead Children's Hospital, Grace Newborn Care, University of Sydney; Dr Jurgen Fripp, Australian e-Health Research Centre, CSIRO Australian e-Health Research Centre; Assoc Prof Leanne Sakzewski, The University of Queensland; Dr Mark Corbett, The University of Adelaide

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 baby if necessary.
- ☐ I/We agree to video recording of assessments for data collection and scoring purposes.
- ☐ 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 share our babies Brain MRI with CSIRO and the ePINO Reserach Team Members.
- ☐ 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			

Family's GP	Printed Name	Address, Phone and Email Contact Details

Note: All parties signing this document must provide their printed name and a date after their signature.

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 this document must provide their printed name and a date after their signature.