PARENT / GUARDIAN INFORMATION SHEET

Formal Title: Early detection of infants at risk or with cerebral palsy: QLD Clinical network

Short title: QEDIN-CP
(Queensland Early Detection and Intervention Network – Cerebral Palsy)

Chief Investigator:	Professor Roslyn Boyd
All Investigators Listed by Site or Hospital and Health Service (HHS)	
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Cairns and Hinterland HHS:	Ms Lynda McNamara, Dr Neil Archer, Dr Marnie Fraser
Central Queensland HHS:	Dr Cheriya Abdulla
Central West HHS:	Dr Clare Walker
Children's Health Queensland HHS:	Dr Priya Edwards, Dr Nicola Previteria, Ms Lisa Findlay
Darling Downs HHS:	Dr John Coghlan
Gold Coast HHS:	Dr Peter Schmidt, Mr Vincent Van Dijk
Mackay HHS:	Dr Jacinta Tobin
Metro North HHS: • Caboolture Hospital • Kilcoy Hospital • Redcliffe Hospital • Community Indigenous Sub-Acute Services • Royal Brisbane & Women's Hospital • The Prince Charles Hospital	Prof Paul Colditz, Dr Pieter Koorts
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Thank you for taking the time to read this Information Sheet

This Information Sheet tells you about the Queensland Early Detection and Intervention Clinical Network – to identify infants at high risk of Cerebral Palsy (QEDIN-CP). It further explains to you clearly and openly all the steps and procedures that might be involved in participation. The information is to help you decide whether or not you and your child would like to be involved in QEDIN-CP.

Before you decide if you and your child want to take part or not, you can ask us any questions you have about the project. You may want to talk about QEDIN-CP with your family, friends, treating doctor or health care worker.

It is ok to say "No"

Important things to know

- It is your choice whether or not your child is involved in QEDIN-CP. You do not have to agree if you do not want to.
- If you decide you do not want your child involved, it will not affect any current or future treatment or care your child receives through any healthcare worker (e.g., doctor) or health service (e.g., hospital).

If you would like your child involved, please sign the consent form provided. 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 being involved in QEDIN-CP

We will give you a copy of this information sheet and the consent form to keep.

What is QEDIN-CP and what is it about?
The QEDIN-CP stands for the Queensland Early Detection and Intervention Network – to identify infants at high risk of cerebral palsy (CP). At the heart of this clinical network are health professionals with special interest and training in the accurate and early identification and care of infants who may be at high risk of having CP or who may have received a diagnosis of CP. Your child may have been screened for "hearing loss" soon after they were born. As we now have accurate ways of determining if your infant is at risk of a later diagnosis of CP we would like you to consider if you would like your infant screened.

There is a new method of determining your infant's risk status of CP that is 98% accurate. It is called the General Movements assessment. It involves a simple video of your infant's spontaneous movements when they are awake and is taken at 3-4 months corrected age (at 12-16 weeks after their due date of delivery). The General Movements assessment is a rating of that video by an expert trained rater from within the network. Your treating clinician would then be informed of the risk status and any follow up assessments or early intervention programs that could be appropriate for your infant.

Cerebral palsy most often impacts movement and posture and it can affect children in many different ways. It is due to damage to the developing brain either during pregnancy or shortly after birth. In Australia, the average age of diagnosis is about 19 months but for some children it can be as late as 2 years of age. Evidence suggests that outcomes for a child may be improved if we can identify CP earlier and provide intervention early.

QEDIN-CP is a clinical network which may assist in earlier identification of all infants at high risk of a later diagnosis of CP who are currently living in Queensland. Earlier detection will ensure appropriate services are engaged to support children and families at an earlier stage and enable children to receive targeted interventions earlier in order to optimise this critical period of brain development. This may lead to improved outcomes for the child, reduced family burden and improved family well-being.

The QEDIN-CP aims to assist your treating clinician in confirming whether your child is at high risk of CP or not.

The QEDIN-CP also wants to assess whether the existence of the network itself does in fact assist in identifying CP earlier.

The ultimate vision of QEDIN-CP is to improve the health and wellbeing of children with CP and their families through early detection and provision of early intervention.

Why am I being asked to participate?
You are being asked to participate in QEDIN-CP because your treating clinician has identified that your child may have some level of risk of having CP (for example, there is something in your child's medical history, they may have been born very early, or had a finding on their early cranial ultrasound (CUS) or brain MRI, or your child's development that may not be tracking as expected).

What is involved if we take part in QEDIN-CP?

PART A – EARLY DECTECTION

We will request information about your child from your treating clinician and we may also need to access your child's medical records including, if available, MRI (brain scan) or cranial ultrasound (CUS) images and reports, hospital discharge summary, etc.

NB. The ages listed below are corrected ages. If your child was born prematurely (that is, less than 40 weeks gestation), the corrected age is your child's chronological age minus the number of weeks or months he/she was born early. Therefore, if your baby was born prematurely, the ages below relate to the number of weeks after your child's expected due date.

If your child was born full term you will just refer to the listed ages.

If your child is between 12 and 16 weeks corrected age:

- QEDIN-CP will guide you (or together with your referring clinician) on the steps involved in taking a video of your infant using a smartphone application (APP). The mobile phone APP will upload the video to our secure database and it will backed up on our secure server. If you do not have a mobile phone or have difficulty recording your infant's movement video at home, we will advise alternate arrangements. If one of your clinicians has already done a video assessment with your infant, they will send QEDIN-CP the video directly via a secure cloud-based platform and it will be backed up on our secure server. If you have had a video assessment as part of another research study, we will ask them to send QEDIN-CP the video directly via a secure cloud-based platform and it will be backed up on our secure server.

- If required, QEDIN-CP will assign a trained health professional(s) within the network to assess your child's General Movements (GMs) on the video.
- The result of the assessment will be sent to your child's treating clinician to discuss with you.
- If your child is identified as being at high risk for CP, you will be informed of early intervention services and/or clinical trials of early interventions that would be relevant to your child. You can then discuss these with your treating clinician.
- At 2 years of age QEDIN-CP will contact you and/or your child's treating clinician to check on your child's outcomes. We will ask them to share the results of any assessments/ baby health checks they may have performed of your child's clinical outcomes at this time.

If your child is >16 weeks corrected age and < 9 months corrected age:

- QEDIN-CP will link you with a health professional who is trained in a standardised assessment called the Hammersmith Infant Neurological Examination (HINE). The HINE consists of 26 items that assess nerve function, posture, quality and quantity of movements, muscle tone, and reflexes and reactions. It typically takes between 10 to 15 minutes to complete the assessment.
- The health professional will video the HINE assessment and send QEDIN-CP the video directly via a secure cloud-based platform and it will be backed up on our secure server. If one of your clinicians has already done the assessment with your infant, the video will be sent to QEDIN-CP via the same method.
- If you have had a video assessment as part of another research study, we will ask them to send QEDIN-CP the video directly via a secure cloud-based platform and it will be backed up on our secure server.
- If required, QEDIN-CP will assign a health professional(s) within the network to score the videoed assessment.
- The results of the assessment will be sent to your child's treating clinician to discuss with you.
- If your child is identified as being at high risk for CP, you will be informed of early intervention services and/or clinical trials of early interventions that would be relevant to your child. You can then discuss these with your treating clinician.
- At 2 years of age QEDIN-CP will contact you and/or your child's treating clinician to check on your child's outcomes.

We will ask you the contact details for your child's grandparent(s) to assist in making contact with you at the 2 year follow-up. We will not contact your child's grandparents unless we have tried all other means of making contact with you (that is via telephone, mail, email).

PART B – FURTHER RESEARCH

An ultimate aim of the QEDIN-CP is to improve the health and wellbeing of children with CP and their families through early detection and early intervention. Therefore, we will also ask you:

- whether or not you would like to allow your child's information/videos to be used for research purposes.
- whether or not you would like to allow your child's information/videos to be used for teaching purposes.

- whether or not you would like to be contacted about any research trials that your child may be eligible to participate in. Full ethical approval would be sought by the research team and a new consent process undertaken.
- whether or not you would like to allow information to be shared between QEDIN-CP and any research study you agree to be screened for or consent to participate in.

You and your child can still be involved in PART A – EARLY DETECTION even if you do not want involvement in any section of PART B Information about Further Research on early intervention (if you answer NO to any question in PART B, it will **NOT** prevent involvement in PART A).

What if I wish to withdraw?
If you decide to participate, you are free to withdraw consent and to discontinue your involvement at any time. The decision to withdraw will not affect any of your child's routine medical treatment or any relationships with the people treating them.

What are the possible risks?
There are no anticipated risks to your child 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 are the possible benefits for my child and other people in the future?
It is possible that involvement with QEDIN-CP may assist in identifying if your child is at high risk of a later diagnosis of CP or in confirming earlier than might have occurred that you child does (or does not) have CP. Earlier detection of being at risk / or having CP may assist in accessing local services or in being referred to trials of new early interventions or family support.

The QEDIN-CP may assist in identifying infants at high risk of CP earlier right across Queensland. Earlier detection will ensure appropriate services are engaged to support the infant and the family at an earlier stage. Early detection will enable families of children to be referred to clinical trials and local services that target interventions earlier in order to optimise this critical period of brain development. This may lead to improved outcomes for the child, reduced family burden and improved family well-being.

What will be done to make sure my child's information is confidential?
All of your child's information (including any videos) will be stored on a password-protected University of Queensland secure server. The filename of any videos will not contain your child's name. Your child's information will be stored in a way that allows the QEDIN-CP coordinators to identify your child's information. However, your child's information will **not** be freely accessible to health professionals within the network. If a health professional is assigned to review your child's video, they will be sent a secure link to the video and information regarding your child's age only.

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/qsa

Research data gathered from QEDIN-CP clinical network may be published, however it will **not** include any information which could enable you or your child to be identified.

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.

Who should I contact for more information?

Professor Roslyn Boyd (Chief Investigator)	Email: r.boyd@uq.edu.au; Telephone: +61 7 3069 7372; Mobile: +61 434608443
Dr Joanne George (Clinical Coordinator)	Email: j.george2@uq.edu.au; Telephone: +61 7 3069 7371
Dr Tracey Evans (Ethics and Governance Coordinator)	Email: t.evans3@uq.edu.au; Telephone: +61 7 3069 7365

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

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CONSENT FORM

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Parent/Guardian Consent to PART A – EARLY DETECTION

I, (Parent/Guardian name) ____,

the parent/legal guardian of (child's name) ____,

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

Mr/Ms/Dr/Professor ____

- I have received the Parent/Guardian Information Sheet (PGIS) to keep and I understand the purpose, extent and possible effects of my child's involvement
- I have been asked if I would like to have a family member or friend with me while the project is explained
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I 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.
- I 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 understand that my child's identity will not be revealed.
- I understand that if I refuse to consent, or if I withdraw my child from the study at any time with or without explanation, this will not affect my child's access to the standard care that all children receive.
- I understand I will receive a copy of this consent form.

	Circle
• I consent for QEDIN-CP to access relevant information from my child's treating clinician and/or medical records (including brain MRI and/or cranial ultrasound, if available)	YES / NO
• I consent to provide the name and contact details of my child's grandparents in order to assist in maintaining contact for the 2 year follow-up.	YES / NO

OPTIONAL PART B – FURTHER RESEARCH

	Circle
• I consent to my child's information/videos being used for research purposes.	YES / NO
• I consent to my child's information/videos being used for teaching purposes.	YES / NO
• I would like to be contacted about any research trials that my child may be eligible to participate in. (NB. full ethical approval would be sought by the research team and a new consent process undertaken)	YES / NO
• I consent for information to be shared between QEDIN-CP and any research study I agree to be screened for or consent to participate in.	YES / NO

____ ____________________

Signature of parent/guardian Date

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

QEDIN-CP representative's name (print): ____

QEDIN-CP representative's signature: ____

Date: ____________________