HEALTH PROFESSIONAL - PARTICIPANT 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)	
The University of Queensland:	Prof Roslyn Boyd, Dr Joanne George
Mater Misericordiae Limited, Brisbane:	Dr Elizabeth Hurrion, A/Prof Luke Jardine, Ms Mandy Proctor
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
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Prof Iona Novak, Dr Cathy Morgan (Cerebral Palsy Alliance), Prof Paul Scuffham (Griffith University), Prof Stephen Rose (CSIRO), A/Prof Anthony Smith (Centre for Online Health).	

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 would like to be involved in QEDIN-CP.

Before you decide if you 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 colleagues and your supervisors.

It is ok to say "No"

Important things to know
- It is your choice whether or not you are involved in QEDIN-CP. You do not have to agree if you do not want to.
- If you decide you do not want to be involved, it will not affect any relationships with any academic or health professional, or current or future relationships with staff from any academic or health institution/organisation.

If you would like to be 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 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?
In Australia, the average age that cerebral palsy (CP) is diagnosed is 19-months (Australian Cerebral Palsy Register), and low-risk term-born infants (50% of all CP cases) frequently do not receive a diagnosis until >2 years. In both instances, the opportunity to capitalise on the early period of maximum brain development and neuroplasticity is being missed.

There are new international clinical practice guidelines for the early detection of CP (Novak et al., *in press*), and assessment tools that can accurately predict CP risk – at 12-16 weeks corrected age (CA) the General Movements (GMs) assessment is 95-98% predictive of CP (Bosanquet et al 2013; Spittle et al 2008), and at >16 weeks CA the Hammersmith Infant Neurological Examination (HINE) is 90-96% predictive of CP (Romeo et al., 2008, 2013, 2016).

Across Queensland there is currently no formal state-wide screening for risk of CP and use of these 'gold standard' assessments is variable. The Queensland Early Detection and Intervention Network - Cerebral Palsy (QEDIN-CP) will unite interested parties and health professionals across Queensland and will support the implementation and maintenance of best practice for the early identification and management of CP.

QEDIN-CP may assist in identifying CP earlier right across Queensland. Earlier detection will ensure appropriate services are engaged to support the child and the family at an earlier stage. Early detection will 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.

QEDIN-CP's Aims:

1. To increase the early detection of infants at high risk or with CP to enable entry into interventions earlier at a time of maximum brain development.

2. To provide information on support for families of infants identified early as being at high risk or of having CP.

3. To increase the early diagnosis of those infants who are not currently identified as being at high risk for CP but have a medical history that indicates that they could potentially be at risk (50% of CP cases).

4. To provide support for clinicians involved in the identification/diagnosis of infants who may have CP.

5. To provide education and training on early detection and early interventions for infants at risk of CP, and the ongoing maintenance of clinical skills for early detection.

QEDIN-CP's Vision: To improve the health and wellbeing of children with cerebral palsy and their families through early detection and early intervention.

QEDIN-CP's Mission: All children impacted by CP in Queensland will be identified and provided with the earliest possible diagnosis to enable best practice early intervention and fast tracking into clinical trials as part of a national strategy for CP.

How will children and their parents be involved in QEDIN-CP?

QEDIN-CP will receive referrals from any treating clinician who thinks a child could potentially be at risk of CP (e.g., there is something in the child's medical history, an abnormal finding on early cranial ultrasound (CUS) or brain MRI, and/or the child's development may not be tracking as expected).

If the child is between 12 and 16 weeks corrected age (CA):

- QEDIN-CP will guide the parent and/or treating clinician to take a video of the infant using a smartphone application (APP) which will upload the video to a secure database and it will backed up on a secure server. If the referring clinician has already done a video assessment, they will send QEDIN-CP the video directly via a secure cloud-based platform and it will be backed up on our secure server.
- QEDIN-CP will assign an accredited health professional(s) within the network to assess the child's GMs on the video.
- The result of the assessment will be sent to the child's treating clinician to discuss with the parent.
- If the child is identified as being at high risk for CP, the parent will be informed of early intervention services and/or clinical trials of early interventions that would be relevant to the child which can be discussed with the treating clinician.
- At 2 years of age QEDIN-CP will contact the parent and/or child's treating clinician to check on the child's outcomes. We will ask them to share the results of any assessments/ baby health checks they may have performed of the child's clinical outcomes at this time.

If the child is >16 weeks and < 9 months CA:

- QEDIN-CP will link the parent with a health professional who is trained/experienced in the HINE.
- 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

the clinician has already done the assessment with the infant, the video will be sent to QEDIN-CP via the same method.

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

Why am I being asked to participate?
You are being asked to participate as you work with children who may be at risk of CP, have an interest in early detection and intervention for CP, and/or are trained in best practice assessments for the detection of CP.

What is involved if we take part in QEDIN-CP?
We will request information about your location of work, discipline/specialty, your desired level of involvement in the network (e.g., informed of QEDIN-CP professional development activities only), and whether or not you are accredited in the GMs assessment or trained/experienced in the HINE.

If you are accredited/trained in the GMs and/or HINE, we will ask you whether you would like to be involved in rating videos of children referred to the network. If you are accredited/trained and agree to rate videos of children referred to the network, as part of the consent process you will be asked to agree to treat all information confidentially. If requested to rate a video, you will be sent a secure link to the video (e.g., Kiteworks, Cloudstor, REDcap) and information regarding the child's gestational age. After rating the video you will be required to delete any downloaded file of the video from your system.

DATA SECURITY AND HANDLING:

All information and videos will be stored on a password-protected University of Queensland secure server. Data will be entered into a REDCap database which enables a high degree of control over levels of access – REDCap data will be stored in an individually identifiable manner. Video file names will be in de-identified but re-identifiable form. Data extracted for research purposes will be in de-identified but re-identifiable form.

Raters will be sent a secure link to the videos (e.g., Kiteworks, Cloudstor, REDCap) and information regarding the child's gestational age only. As part of the health-professional consent process, raters will be asked to agree to treat all information confidentially and to delete any downloaded file of the video from their system.

Copies of digital letters providing feedback to the child's treating clinician will be stored within a password-protected folder on a University of Queensland secure server. Signed consent forms will be scanned and saved as digital files within a password-protected folder on a University of Queensland secure server. Paper copies will be disposed of via a secure shredding service. All data/information including videos will be backed up 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/qsa

Any data published will be completely de-identified so as not to reveal the identity of any participant or health professional.

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

CONSENT FORM

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Name of Health Professional: _____

Discipline / Specialty: _____

Organisation: _____

Physical Location: _____

Postal address: _____

_____

_____

Email address: _____

Work telephone number: _____

- I have received the <u>Health Professional – Information Sheet</u> to keep and I understand the purpose and extent of my involvement
- I have been informed that I may want to talk about QEDIN-CP with my colleagues or supervisors.
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I understand if I decide I do not want to be involved, it will not affect any relationships with any academic or health professional, or current or future relationships with staff from any academic or health institution/organisation.
- I understand I will receive a copy of this consent form.

Circle

- I consent to receive information from QEDIN-CP regarding network meetings, QEDIN-CP updates, and professional development activities/opportunities.   YES / NO

Circle

Are you accredited in the General Movements assessment?   YES / NO

If yes, please indicate:

	Year accredited	Location of training
☐ Basic	_____	_____
☐ Advanced	_____	_____

Circle

Do you have training / experience in the Hammersmith Infant Neurological Examination?   YES / NO

If you are accredited in GMs and/or trained in the HINE, please indicate the level of involvement in QEDIN-CP by circling the applicable responses to the statement/questions below:

- If you are accredited in the General Movements assessment, do you consent to be contacted regarding the rating of children within your current unit?   YES / NO

- If you are accredited in the General Movements assessment, do you consent to be contacted regarding the rating of children within your current region?   YES / NO

- If you are accredited in the General Movements assessment, do you consent to be contacted regarding the rating of children outside of your region?   YES / NO

- If you are trained/experienced in the Hammersmith Infant Neurological Examination, do you consent to be contacted regarding the rating of children within your current unit?   YES / NO

- If you are trained/experienced in the Hammersmith Infant Neurological Examination, do you consent to be contacted regarding the rating of children within your current region?   YES / NO

- If you are trained/experienced in the Hammersmith Infant Neurological Examination, do you consent to be contacted regarding the rating of children outside of your region?   YES / NO

_____   _____

Signature of health professional   Date

If you have consented to be a rater for the GMs and/or HINE, do you agree to treat any information you receive from QEDIN-CP confidentially and to delete any videos that you rate?

I, (print health professional's name) _____, agree to treat any information I receive from QEDIN-CP confidentially and to delete any videos that I rate.

_____   _____

Signature of health professional   Date

I have explained the project to the health professional who has signed above, and believe that they understand the purpose and extent of their involvement in this project.

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

QEDIN-CP representative's signature: _____

Date: _____