PARENT/ GUARDIAN INFORMATION SHEET

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

What is an Information Sheet?
This 4 page Information Sheet tells you about the research project. It explains the steps, and how they will happen. This is to help you decide if you and your baby want to join the research project. Please read this Information Sheet carefully. You can ask us anything you want to know about it. You might also want to go through it with your family, friends, or health care worker.

It’s ok to say ‘no’. If you don’t want your baby to take part, you don’t have to. You can stop at any time, and you don’t have to explain ‘why’. Saying ‘no’ will not change any of your baby’s medical care or services they get.

If you want to join the research project, we will give you a consent form to sign.

What is this research project about?
We can check for certain movement and learning difficulties (cerebral palsy and adverse neurodevelopmental outcomes – see factsheet) in babies from as young as 3 months. We want to know how correctly we can identify babies with different types of movement and learning difficulties. We also want to know if a home-based program provided by Aboriginal and/or Torres Strait Islander Health Workers is helpful for you and your family.

How will this study support me and my baby?
If we find out about movement/ learning difficulties early (including cerebral palsy and adverse neurodevelopmental outcomes), we can start play-based support straight away. We think this will give your child the best chance of developing well. This might be better movement, learning, talking, growth, and other health outcomes. We can also link you to other support, including NDIS if you qualify.

How will this study help other people in the future?
If this program is helpful for your baby, you, and your family, we can share the program with other Aboriginal and/or Torres Strait Islander communities, particularly those in rural and remote communities.

Is the LEAP-CP project safe for my baby? The tests and home-based support are considered to be safe; they are all play-based and not invasive. There are no extra risks for you or your baby. Your baby might not like doing some of the assessments because they feel unfamiliar for them. Your baby should keep seeing their usual doctors and using other helpful services.

What are the possible inconveniences?
We are testing your baby to see if they have movement/ learning difficulties (like cerebral palsy or adverse neurodevelopmental concerns). This might make you feel worried or anxious and you might not want to know about this. By finding out about difficulties early, your baby has the best chance of developing well.

We want this program to support you and your baby. Your visits will be conducted at home (or another place which is good for you and your baby). You can make a time that suits you and your Aboriginal and/or Torres Strait Islander Allied Health/ Community Worker or Aboriginal and/or Torres Strait Islander Health Liaison officer. If you would like to be in the LEAP-CP study you will have to give enough time to do the tests (at the beginning, middle and end), see your Allied Health Worker each week, and regularly practice the games that are shared.
What happens if I decide to join this research project?

There are 2 steps: the first is checking if your baby has any movement or learning difficulties. If they do, you can decide whether you want to receive the home support.

**STEP 1: Checking for movement and learning difficulties**

**When your baby is newborn & 3 months old (or later if your baby was born preterm)**

Someone from our research team will video 5 minutes of your baby’s movement while your baby is still in hospital. You can then do this same video at home at 3 months (twice) on your smartphone. Your local healthcare worker can help if you like. This video will be checked by a doctor or therapist (see factsheet).

**When your baby is 6 months old**

Someone from our research team will check your baby’s movements which will take about 30 minutes. This will be videoed for checking by a doctor or therapist.

**Getting information from you (the caregiver):**

- About the pregnancy and birth
- About who is in the household and who cares for the baby
- What your baby can do
- What medical appointments your baby has
- Your mental health

**Getting information from your baby’s medical file:**

- Brain images (if they have any)
- Doctor’s and other medical reports

**Good result on the tests**

- Probably not a movement or learning difficulty
- Don’t qualify for home support

**Follow up when your baby is 1 year old**

- To see how they are moving and learning, including diagnosis

**Some things to worry about:**

- We want to have more of a look at your baby’s movement and learning

**STEP 2:**

Giving support to both baby and you at home through the LEAP-CP study
STEP 2: Giving you support at home

If you decide you want us to give you support at home, an Aboriginal and Torres Strait Islander Health Worker may continue to see you each week for about 8 months. You and your baby will have up to 4 visits from a health professional (physiotherapist/occupational therapist). Each will take about 2 hours. One check will be at the beginning, then at 12 months, then when you finish the home support program, and finally when your baby is 2 years old. Each time your baby has a longer check, we will do these things:

Checking your baby (videoed):
- Movement, like reaching, sitting, standing
- Learning and talking
- Vision/eyes
- How well they are growing

Gathering information from you (the caregiver):
- What your baby can do
- What things your baby has to learn from at home
- What family and social support you have
- Your mental health

We will ask you for the contact details for other family members (grandparent, aunty, uncle, mum, dad, or carers) to help us keep in touch. You only need to give us ones you are happy to share. We will only use these if we have trouble getting in touch with you. Other family members are welcome to join in the appointments if you would like them to.

Once you and your baby have completed the first test, you will be put in one of 2 groups (by chance), the play program or health advice. We don’t know which of these groups is best.

**Play Program:** weekly home visit (1 hr) by Aboriginal or Torres Strait Islander Health Worker
- Education (how your baby learns, interacting with your baby, helping you cope, feeding & nutrition, health)
- Specific exercises based on goals you choose (communication, play, reaching, sitting)
- Play ideas using materials from your home
- Continued access to existing services in the community

**Health Advice:** monthly home visit by Allied Health Worker
- Infant health advice about feeding, nutrition & general health
- Continued access to existing services in the community
Who is involved in this project?
The Queensland Cerebral Palsy and Rehabilitation Research Centre at The University of Queensland is partnering with local agencies, including Townsville University Hospital, Queensland Children’s Hospital, and your local health care centre to conduct this project. Ms Carly Luke and Ms Leeann Mick-Ramsamy are completing higher degrees (PhD) as part of this project. We have funding to do this project from the National Health and Medical Research Council (Australian Government), Cerebral Palsy Alliance and Children’s Hospital Foundation.

What will we do to make sure your personal information is kept safe?
Information from your tests and videos will be kept on the computer without your or your baby’s name (we can find their name again by looking at a different file). These files are protected by passwords. The paper files will be kept in a locked filing cabinet in an office at the University, without your or your baby’s name. Only the researchers and the centre management team will have access to this information.

Any information we get while you’re doing this project will remain confidential. It will only be shared with others with your permission, except as required by law or for purposes of mandatory reporting.

We will keep your and your baby’s information and videos until they are 33 years old (15 years after they turn 18). This is based on laws and government directions, including the Public Records Act 2002 and the Queensland State Archives’ State Archivist [https://www.qld.gov.au/dsiti/qsa](https://www.qld.gov.au/dsiti/qsa).

If you agree, your information will be used to answer other questions too. We want to understand how the Queensland Early Detection and Intervention Network (QEDIN) has helped to change early screening for babies who might have later difficulties with learning and moving. The knowledge Translation of Early Cerebral Palsy study (KITE-CP) also looks at early screening for babies who might have a later diagnosis of cerebral palsy. If you choose to share your information with these studies, the only extra requirement for you is a short phone call when your baby is 2 years old to see what your baby is learning and doing at that time. Your information and videos may also be kept (if you agree) and used to answer other questions in future research projects at the Child Health Research Centre.

If we give talks or write about the results of this project, we will not use any names. The whole database without any names or identifying details could be made available to other researchers if they provide an appropriate request.

Will I be told about the research results at the end?
If you want more information about your baby’s results, you can ask your doctor, Allied Health Worker or someone from the research team. You can also ask us if you want copies of publications made from this project.

- You can decide if you want you and your baby to join this research project.
- You can stop doing the research project any time you want. You don’t have to explain why.
- If you decide to stop doing the research project, it won’t change anything. Your medical care and other services will stay the same. Your relationship with the doctors and health workers will stay the same.
- You might like to chat with your family or your doctor about joining this research project.
- You can ask for more information before you decide whether to join.
If you have any questions, please contact:

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<th>Name</th>
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<tbody>
<tr>
<td>Professor Roslyn Boyd</td>
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<td>(Chief Investigator)</td>
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<tr>
<td>Ms Lucy Fogarty</td>
<td><a href="mailto:Lucy.fogarty@health.qld.gov.au">Lucy.fogarty@health.qld.gov.au</a></td>
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<tr>
<td>(Study Coordinator)</td>
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<tr>
<td>Ms Carly Luke</td>
<td><a href="mailto:carly.luke@uqconnect.edu.au">carly.luke@uqconnect.edu.au</a></td>
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<td>(Screening study)</td>
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Complaints or ethical issues:
This study has been given ethical approval by the Far North Queensland Human Research Ethics Committee and The University of Queensland Human Research Ethics Committee. It has also been approved by Apunipima Cape York Health Council Research Governance Committee.

Here are some people you can call if you’d like to discuss the study with someone not directly involved. You might have questions about how the study is being run. You might have concerns about your rights as a participant. You might want to make a confidential complaint:

- Far North Queensland Human Research Ethics Committee: Level 7, William McCormack Place 2, 5B Sheridan Street Cairns; 07 4226 5513
- The University of Queensland Human Research Ethics Committee: 07336 53571
- Apunipima Cape York Health Council Research Governance Committee: 07 4037 7213
STEP 1: PARENT/ GUARDIAN CONSENT FORM FOR SCREENING

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

By signing this consent form, I declare that I accept my baby and I participating and that I have understood the following:

- If my baby is demonstrating strong movements (green) on the screening assessment that this means they probably don’t have a movement/ learning difficulty (adverse neurodevelopmental outcome). This means they do not qualify for the parent/caregiver home support program.
- The reason for doing the study, benefits, and negatives of the study as described in the information sheet.
- That my baby and I may not personally direct benefit from joining the study.
- I can freely choose whether to join the research project. I can stop doing it at any time.
- I have been given information and the opportunity to ask questions.
- The information in this sheet may be stored in a research database for the purpose of this study.
- That any publication of the results will not include any names or identifying details.
- I have given a copy of the participant information sheet and consent form to keep.

☐ I consent for the research team to access relevant information from my child’s treating clinician and/ or medical records (including brain MRI, cranial ultrasound, birth history, discharge summary).
☐ I consent for LEAP-CP to share information with any medical teams or clinical services my child is involved with or has been referred to, and for them to be involved in communicating the results to me.
☐ I consent to the referring clinician being informed of my infant’s screening assessment outcome, and for them to be involved in communicating the results to me.
☐ I consent for LEAP-CP to add information and results from my child’s assessments to be added to my child’s medical records
☐ I consent to my information being shared with two other studies – the Queensland Early Detection and Intervention Network (QEDIN); and Knowledge Translation of Early Cerebral Palsy (KITE-CP). This involves an additional phone call at two years of age.
☐ I consent to provide the name and contact details for a second designated contact in order to assist in maintaining contact for the 12 month and 2 year follow up.
☐ I consent my child’s information and videos to be used to answer other questions at the Child Health Research Centre.
☐ I consent for my child’s information/videos being used for teaching and training purposes including medical conferences, seminars, lectures for teaching health professionals.
☐ I consent for my child’s images and videos to be used in publications such as reports, brochures, medical journals and medical conference posters.
☐ I consent to being contacted by the research team to request my participation in the future for follow-up studies.

FNQ PICF LGIS 9/9/2021 Version 2.2
Participant name (print): ____________________________

Parent/caregiver name (print): ____________________________

SIGNATURE ____________________________ Date ____________

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

Researcher’s name (print) ____________________________

SIGNATURE ____________________________ Date ____________

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

Verbal consent provided ____________________________ Date ____________

Researcher’s name & signature ____________________________ Date ____________
STEP 2: PARENT/ GUARDIAN CONSENT FORM FOR INTERVENTION

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

By signing this consent form, I declare that I accept my baby and I participating in the LEAP Allied Health Therapy Program and that I have understood the following:

- The purpose, methods, risks, and inconveniences of the study as described in the information sheet.
- That I may not personally directly benefit from joining the study.
- I can freely choose whether to join the research project. I can stop doing it at any time.
- I have been given information and the opportunity to ask questions.
- The information in this sheet may be stored in a research database for the purpose of this study.
- That any publication of the results will not include any names or identifying details.
- I have been given a copy of the participant information sheet and consent form to keep.

Participant name (print):

__________________________________________

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Researcher’s name & signature Date ____________

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