Children's Health Queensland - The Lady Cilento Hospital
PARENT/GUARDIAN INFORMATION STATEMENT AND CONSENT FORM

Research Project Title: Predict CP: Implementation of Comprehensive Surveillance to Predict Outcomes for Children with Cerebral Palsy

Researchers: Prof Roslyn Boyd, Prof Peter Davies, Prof Jenny Ziviani, Prof Stewart Trost, Dr Lee Barber, Dr Robert Ware, Dr Koa Whittingham, Prof Stephen Rose, A/Prof Jennifer Whitty, Dr Kristie Bell, Dr Christopher Carty, A/Prof John Walsh, Ms Megan Kentish, Dr Priya Edwards, Dr Lisa Copeland, Dr Kelly Weir, Dr Leanne Sakzewski, Dr Andrea Guzetta, Dr Denise Brookes, Prof Alan Coulthard, Mr Owen Lloyd, Dr Steven Obst, Dr Katherine Benfer, Dr Nicolas Dowson, Dr Jurgen Fripp, Dr Kerstin Pannek, Prof Paul Scuffham , A/Prof Joshua Byrnes, A/Prof Martin Downes, A/Prof Richard Norman, Ms Meredith Wynter, Ms Sarah Reedman, Ms Felicity Read, Ms Camilla Davenport, Ms Christine Finn, Ms Kym Morris, Ms Catherine Mak, Ms Andrea Burgess, Ms Jane Wotherspoon, Ms Denni Purcell, Dr Tracey Evans, Dr Shaneen Leishman, Dr Adriana De Santos, Ms Mina Bahrampour, and Ms Emily Johnson.

Thank you for taking the time to read this Information Statement. This Information Statement and Consent Form is 15 pages long. Please make sure you read all pages.
For people who speak languages other English: If you would also like information about the research and a Consent Form in your language, please ask the person explaining this project to you.

You are asked to participate in the research project that is explained below.

What is an Information Statement?
These pages tell you about the research study. It explains to you all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully. You are welcome to ask us questions about anything in it. You may wish to talk about the project with your family, friends or health care worker.

Do I have to participate?
Your participation in this research is entirely voluntary and there will be no cost to you**.** If you do not want to take part in this study you don't have to. Choosing not to take part in this study will not affect your current and future medical care in any way.

Withdrawing from the study
If you do consent to participate, you may withdraw at any time, without explanation. If you do withdraw, you will be asked to complete and sign the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively, you can withdraw from the study at any time by contacting Prof Roslyn Boyd by phone (07 3069 7372) or email (r.boyd@uq.edu.au). The decision to withdraw from the study will not affect your child's routine medical treatment or their relationship with the people treating them. If you decided to leave the research study, the researchers will not

collect additional information from you. The information collected about you up to that point will be retained unless you tell us not to. Data may not be able to be deleted if we have analysed and/or published the research results. In this case, your privacy will continue to be protected at all times. If you withdraw from the research before MBS/PBS information is collected, we will not collect your MBS/PBS information. MBS/PBS information collected prior to your withdrawal will be retained unless you tell us not to. You may like to discuss your child's participation in this research project with your family and with your doctor. You can ask for further information before deciding to take part.

What is this research project about?
This project is about the relationship between brain development and physical capacity, growth, physical activity, communication, cognition and educational outcomes of children who have cerebral palsy. Cerebral Palsy is a physical disability caused by early brain injury. It occurs in 1 in 500 children. This project will provide comprehensive assessment of outcomes that will inform the development of timely and effective interventions and predict future outcomes for children with cerebral palsy.

Why is my child being asked to be in this research project?
We are asking your child to take part because he/she has cerebral palsy, was born in Queensland in one of the following years: 2006, 2007, 2008, 2009, 2010, or 2011 and may or may not have previously taken part in one of the Queensland CP Child studies.

What are the alternatives to taking part in this project?
There is no requirement to participate in this project. Should you choose not to participate in this project, your child will have all the usual access to treatment at Children's Health Queensland.

What does my child need to do to be in this research project?
Your child will be seen on one occasion at a time between their 8th and 13th birthdays. The assessments will take a total of 8 hours if your child is ambulant, and 6 hours if your child is non-ambulant, administered over 1-1.5 days. You and your child will be asked to complete some questionnaires at home prior to the visit (2 hours).

The following assessments will be performed:-

a. **Movement, learning, language, and communication assessments**
   A range of movement, learning, language, and communication assessments will be completed by suitable healthcare professions (e.g., physiotherapist, occupational therapist, research psychologist). Some of the assessments will involve direct participation of your child through a series of play-based (board games, solving puzzles) and school-based activities (vocabulary, reading, numerical operations, spelling). If your child has been diagnosed with a dyskinetic type of cerebral palsy (i.e. dystonia, choreoathotosis), he/she will be videoed performing simple movements to assess the impact of their dyskinesia. For other assessments you will be asked to complete questionnaires in relation to your child's development, behaviour, participation, quality of life, and health-related resource use, as well as your feelings about parenting.
b. **Body structure**
   We will measure you child's height and weight to assess growth and body mass for age. A Dual Energy X-ray Absorptiometry (DXA) scan, which is used to measure the density or strength of bones, will also be conducted to determine your child's overall bone health. A DXA scan is safe tool that is routinely used in clinical practice. You will also have the option of providing consent for a blood test to determine your child's levels of vitamin D

and other nutrients related to bone health. These blood tests will provide helpful information for the study; however, you can participate in the study even if you choose for your child not to have the blood tests.

c. Feeding evaluation

Your child will be provided a small snack to consume during your visit. Your child will be videotaped whilst eating this snack to determine if they have any difficulties with eating.

d. Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data

A record of medical and pharmaceutical services utilised by your child, including direct costs of treatment. You will be asked to fill out a consent form authorising the study access to your child's/your complete MBS and PBS data as outlined on the back of the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. If your child is on two Medicare cards, both card numbers and the signatures of the primary card holders will need to be on the child consent form. Data will only be supplied for the card consented to in these instances. If your child turns 14 years of age during the study, they will need to complete and sign the participant consent form themselves or be signed by a Power of Attorney or legal guardian (evidence will need to be provided). This may mean there will be more than one consent form for your child. The consent form/s will be sent securely to the Department of Human Services who holds this information confidentially.

e. Valuation study of the Cerebral Palsy six dimension classification system (CP-6D; pilot study)

This classification system is a short version of the quality of life assessment and captures the most important factors affecting health-related quality of life. Specifically, you will be asked about your child's social wellbeing and acceptance, physical health, communication, pain and discomfort, sleep, and emotional wellbeing.

f. Home activities

Following your appointment your child will be asked to wear a small activity monitor (Actigraph) for seven days and you will be asked to complete sun exposure and food diaries (7 and 3 days respectively).

g. Activity outcomes for ambulant children

If your child **can walk independently with or without a walking aid** then the following assessments will be performed:

i. Leg muscle size, structure and function using ultrasound on their calf muscle
ii. Gait quality using 2D video analysis of their walking
iii. Functional strength using a 30 seconds repetition maximum test for lateral step up, sit to stand and stand from kneel exercises
iv. Walking speed over 10 metres, anaerobic power during a 15 metre shuttle run test, and walking ability during a 6 minute walk test
v. Walking quality will be assessed using the Queensland Children's Gait Laboratory standardised 3D gait analysis procedure and whole body 3D gait kinematics will be computed. Children will be asked to walk at a self-selected speed over a level walkway 10 times, barefoot. Small reflective markers will be attached to the head, trunk, pelvis, and upper and lower limbs to measure movement of the limbs as the child walks.

h. Magnetic Resonance Image Scan (MRI) of your child's brain

The MRI will include taking pictures of your child's brain while he/she is resting on their back, and then while he/she is moving his/her hand. MRI is safe. There is no ionizing

radiation and it has no known dangerous or harmful effects. It is painless and your child will be awake as no sedation or any other drugs are given.

We will ask your child to lie on a table inside the MRI scanner. Some people feel uncomfortable in the MRI scanner because of the tight space. To help make your child feel comfortable he/she will be offered to watch an age-appropriate movie and to undertake some preparation to be familiar with the MRI and tasks we will ask them to do. Your child can withdraw from the MRI scan at any time, before and also during the scan. A member of our team will stay with your child at all times. We are also in constant communication with your child via a two-way intercom system. The test should take approximately 1-1.5 hours to complete, but only 30-45 minutes of this time will be spent inside the scanner. Although the MRI is offered and may provide helpful information, your child can participate in the study even if you choose not to have the MRI scan.

Video and audio recording

We would like to video and audio record the assessments (with your consent) for quality assurance and scoring purposes. You are under no obligation to consent to your child being video and audio recorded, and you are free to stop the recording at any time. If your child is videotaped it may be possible to identify them in the video. Video tapes of the assessments will be stored in an individual file for your child in a secure, locked, fire proof filing cabinet and only the researchers will have access to this information. We will label the recordings with a number instead of your child's name.

How will this study benefit my child?

This study will provide you with information about your child's growth, bone health, dietary intake, cognitive/intellectual functioning, executive functioning behaviours and estimated academic achievement. You will have the opportunity to discuss your child's progress and any concerns with the research team. The final study results will be summarized and reported back to you at the conclusion of the study. The results can be made available to your Paediatrician/Rehabilitation Specialist/GP or treating clinician (with your consent), whom may then refer you for treatment if they believe necessary. You will have the opportunity to have an MRI of your child's brain. This will be helpful in the future for predicting the outcomes of children with CP. You will have the opportunity to discuss your child's progress and any concerns with the research team.

How will this study benefit other people in the future?

The results of this study will provide valuable information that will help us to identify the predicted outcomes of children with cerebral palsy based on their brain MRI and outcomes. It will also help us determine why some children with cerebral palsy grow poorly and how poor growth, dietary intake, bone health and physical activity may impact on their quality of life, participation and the amount of health care used. It will also assist us to determine which children need help to improve their nutrition, growth, bone health and physical activity and at what age is the best time to do this.

What are the risks for my child?

There are no additional risks for your child with these measurements (including Magnetic Resonance Imaging (MRI), DXA and ultrasound) over and above that experienced during routine blood tests or clinical examinations with their doctor. All procedures are frequently used for both clinical and research purposes. This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.11 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low. The blood tests will be performed at the hospital by

experienced personnel and require only one blood sample. In the case of an emergency, expert staff and medical facilities are located in the immediate testing vicinity. This will keep risks, if any, to an absolute minimum.

You are under no obligation to consent to your child having the blood test or a brain MRI scan.

What happens if something abnormal or unexpected is found in my child's MRI scan?
In this study, we will take a number of pictures of your child's brain, or will review pictures that have already been taken. After your child's scan, a specialist will examine these pictures. This will not be done on the day of the scan. With cerebral palsy there is a high chance of finding an abnormality on the brain scan. There is also the possibility that the scan will show up something in your child'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 scan are distressing for you, we will offer you counseling with specially trained staff.

What happens if something abnormal or unexpected is found in my child's DXA scan?
In this study, the DXA scan is performed by a qualified bone densitometry technician, who has undergone specialist training with the Australian and New Zealand Bone and Mineral Society. After your child's scan, the technician will examine these scans. This will not be done on the day of the scan. In very rare cases, the scan may show a bone abnormality. 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 scan are distressing for you, we will offer you counseling with specially trained staff.

What happens if something abnormal or unexpected is found in my child's bloods tests?
In this study, Pathology Queensland, the company that carries out blood collection and testing for many Queensland hospitals, including the Lady Cilento Children's Hospital will analyse your child's blood tests. The tests carried out will include measures of bone health, including Vitamin D and Calcium. After your child's blood collection, the Pathology Queensland technicians will carry out testing and the study researchers will assess the results. This will not be done on the day of the blood test. We will provide the results of the blood tests to a rehab physician for review, who will forward those to your child's preferred Paediatrician/ GP if any results require follow-up. There is the possibility that the tests will show up something in your child's blood that we had not expected. In many cases, this is likely to be significant, but not something of great concern and can be followed up with your child's usual doctor, for example low vitamin D levels. In very rare cases, the blood test may show another abnormality. 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 tests are distressing for you, we will offer you counseling with specially trained staff.

What are the possible inconveniences?
The MRI scanner is noisy, so protective earmuffs will be placed over your child's ears during the scan. The assessment appointments will be planned to minimize any inconvenience to you and to coincide with any other appointment that you may have at the hospital. The assessments will take between 2.5 and 9.5 hours in total over 1-2 visits. We will provide parking at both the MRI and clinical assessment facilities during these visits. In addition, once home, you will be required to complete a 3 day food diary and a 7 day sun exposure diary. Your child will also be asked to wear a physical activity monitor for 7 days.

What will be done to make sure the information is confidential?
All results of assessments/questionnaires will be stored securely on an electronic database with your child's study number and not their name. Data collection sheets recording the assessments and the

videotapes of the assessments will be stored in an individual file for your child in a secure, locked, fire proof filing cabinet. Only the researchers will have access to this information. 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. All names and identifying information will be removed from data prior to any analysis. If we give talks or write about the results of this project, we will not use any names.

Your child's MBS and PBS data information will remain confidential and will not be disclosed without your permission, except as required by law. You can withdraw your consent later. Your child's MBS and PBS data will be stored without your child's name. A number (as mentioned above) will be used to identify them. Your child's coded MBS and PBS data will be held securely and confidentially by our study team members at the Queensland Cerebral Palsy and Rehabilitation Research Centre to enable us to identify resource use and direct costs of treatment. The MBS and PBS data cannot be used for any other purposes other than the study approved. The resource use and cost data from this study will be stored securely for 7 years from the end of the study, after which it will be destroyed securely.

Will I be informed of the results when the research project is finished?
You will receive a written report with some of the results of your child's assessments. If at any time you would like more information about your child's results, an appointment may be organised with one of the researchers. A regular newsletter will also be sent to you about the progress of the study. At the end of the study all families will be sent a summary of the results. The newsletters and final summary will talk about the children as a group and your child will not be identified in person.

What about other research studies?
Data may continue to be useful to researchers for many years to come. Advances in our knowledge may make it important for researchers to re-examine data several years from now. With your consent, data may be shared with other researchers (within and outside of Australia), including for other projects. Before any future work proceeds, it will need to be reviewed by an ethics committee. Data may be analysed in conjunction with information collated in previous, or future, studies conducted by the chief investigator Prof Roslyn Boyd.

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

Name: Dr Shaneen Leishman, Clinical Research Coordinator**,** Queensland Cerebral Palsy and Rehabilitation Research Centre, Centre for Children's Health Research, The University of Queensland
Contact telephone: (07) 3069 7354 **OR**
Chief Investigator: Prof Roslyn Boyd, Professor Queensland Cerebral Palsy and Rehabilitation Research Centre, Centre for Children's Health Research, The University of Queensland
Contact telephone: (07) 3069 7372 **mobile:** 0434 608 443

What are my child's rights as a participant?
I am informed that except where stated above, no information regarding my child's medical history will be released. This is subject to legal requirements. I am informed that the results of any tests involving my child will not be published so as to reveal my child's identity. This is subject to legal requirements. The detail of the procedure proposed has also been explained to me. This includes how long it will take, how often the procedure will be performed and whether any discomfort will result. It has also been explained that my child's involvement in the research may not be of any benefit to him or her. I understand that the purpose of this research project is to improve the quality of medical care in the future. I have been asked if I would like to have a family member or a friend with me while the project is explained to me. I understand that this project follows the guidelines of the National Statement on Ethical Conduct in Research Involving Humans (1999). I understand that this research project has been approved by the Children's Health Services Human Research Ethics Committee (CHS HREC) on behalf of Children's Health Queensland. I have received a copy of this document.

Contact:- The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning policies, information about the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, at any time, you may contact the Coordinator of the Ethics Committee on 3069 7002 or email CHQETHICS@health.qld.gov.au.

This study adheres to the Guidelines of the ethical review process of The University of Queensland. Whilst you are free to discuss your participation in this study with the Clinical Research Coordinator for PREDICT (contactable on 07 3069 7354), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on 3365 3924.

STANDARD INFORMED CONSENT FOR PARENT/GUARDIAN TO GIVE CONSENT FOR THEIR CHILD TO PARTICIPATE IN A RESEARCH PROJECT

Project Number

HREC No: HREC/14/QRCH/329

Title of Project

Predict CP: Implementation of Comprehensive Surveillance to Predict Outcomes for Children with Cerebral Palsy

Investigator(s)

Prof Roslyn Boyd, Prof Peter Davies, Prof Jenny Ziviani, Prof Stewart Trost, Dr Lee Barber, Dr Robert Ware, Dr Koa Whittingham, Prof Stephen Rose, A/Prof Jennifer Whitty, Dr Kristie Bell, Dr Christopher Carty, A/Prof John Walsh, Ms Megan Kentish, Dr Priya Edwards, Dr Lisa Copeland, Dr Kelly Weir, Dr Leanne Sakzewski, Dr Andrea Guzetta, Dr Denise Brookes, Prof Alan Coulthard, Mr Owen Lloyd, Dr Nicholas Dowson, Dr Katherine Benfer, Dr Steven Obst, Dr Jurgen Fripp, Dr Kerstin Pannek, Prof Paul Scuffham, A/Prof Joshua Byrnes, A/Prof Martin Downes, and A/Prof Richard Norman

I (Parent/Guardian name) _____

voluntarily consent for my child to take part in the above titled Research Project, explained to me by

Mr/Ms/Dr/Professor _____

Child's Name _____

Address _____

Contact Phone Numbers _____

- I have received a Parent/Guardian Information Statement to keep and I believe 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 was explained
- I have had an opportunity to ask questions and I am satisfied with the answers I have received
- I understand that the researcher has agreed not to reveal results of any information involving my child, subject to legal requirements
- If information about this project is published or presented in any public form, I understand that the researcher will not reveal my child's identity
- I understand that data collected may be shared with other researchers (within and outside of Australia) and/or other studies conducted by the chief investigators
- I understand that if I refuse to consent to my child's participation, or if I withdraw my child from the project at any time without explanation, this will not affect my child's access to the best available treatment options and care from Children's Health Queensland. **If you do not wish to participate, it is okay to say no**
- I understand I will receive a copy of this consent form

I consent for my child to be video and audio recorded for the purpose of research assessment	❑ **yes**	❑ **no**
I consent for the summary report of my child's progress from the study to be included in the hospital record (please tick):	❑ **yes**	❑ **no**
I consent for my child to receive the Brain MRI scan (please tick):	❑ **yes**	❑ **no**
I consent for my child to have the blood test described (please tick):	❑ **yes**	❑ **no**
I consent for my child's individual NAPLAN results to be released by the Queensland Curriculum and Assessment Authority (QCAA) (please tick):	❑ **yes**	❑ **no**
I authorise the Department of Human Services to provide my child's MBS and PBS claims history (please tick):	❑ **yes**	❑ **no**
I consent to completion of the CP-6D about my child's health state (please tick):	❑ **yes**	❑ **no**

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 child's involvement in this study.

RESEARCHER'S SIGNATURE _____ **Date** _____

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

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of my child's Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) information by the Department of Human Services (DHS) to the Queensland Cerebral Palsy Rehabilitation and Research Centre, the University of Queensland, for the purposes of the Predict CP Study

Important Information
Complete this form to request the release of your child's Medicare claims information and/or your PBS claims and .or AIR information to the Predict CP Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

Rights and Privacy:
I understand that:
☐ my child's MBS and/or PBS information will be disclosed by DHS for the purposes of the study.
☐ the results of this research may be published in articles or journals.
☐ my child's real name will never be disclosed by DHS, used in the study or published.
☐ my child's participation in the study is completely voluntary.
☐ I can withdraw my child's participation in the study at any time.

Consent:
☐ I understand the information provided to me about the study my child is participating in.
☐ I have been given the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.
☐ I consent to the disclosure by DHS of my child's MBS and/or PBS information to researchers for the purposes of the study.

PARTICIPANT DETAILS
1. Master ☐ Miss ☐

Child's family name: _____ Child's first given name:_____

Child's other given name (s): _____ Child's date of birth: ___/___/_____
DD / MM / YYYY

2. Child's Medicare card number **1:** _____ **2:** _____

3. Child's primary address: _____

Child's secondary address: _____

Postal address (if different to above): _____

AUTHORISATION
4. I authorise the Department of Human Services to provide my child's:

☐ Medicare claims history OR

☐ PBS claims history OR

☐ Medicare & PBS claims history

For the period* ___ /____ /_____ to: ___ /___ /_____ to the PREDICT CP Study.
DD /MM / YYYY DD / MM / YYYY

*Note: As the Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.

DECLARATION
I declare that the information on this form is true and correct.

5. Signed: _____(parent's signature) Dated: ___ /____/_____
DD / MM / YYYY

Signed: _____(parent's signature) Dated: ___ /____/_____
DD / MM / YYYY

OR

6. Signed by _____ (full name) _____ (signature of legal guardian/POA)

Dated: ___ /____/_____
DD / MM / YYYY

☐ Parent (where the participant is under the age of 14 years old*)

☐ Legal guardian** (where the participant is under the age of 14 years old*)

☐ Power of attorney** ☐ Guardianship order**

* Once a young person has turned 14 years old they must consent to their own information being released.
** Please attach supporting evidence

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your child's Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type	Hospital Indicator	Item Category
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash	N	1
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill	N	2

A sample of the information that may be included in your PBS claims history:

Date of supply	PBS item code	Item description	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	ATC Code	ATC Name
06/03/09	03133X	Oxazepham Tablet 30 mg	$5.30	$25.55	N05 B A 04	Oxazepam
04/07/09	03161J	Diazepam Tablet 2 mg	$30.85		N05 B A 01	Diazepam

** Under co-payments can now be provided for data after 1 July 2012

APP 5 – PRIVACY NOTICE

Your personal information is protected by law (including the Privacy Act 1988) and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services.

Your information may be used by the department, or given to other parties where you have agreed to that, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

You can get more information about the way in which the department will manage your personal information, including our privacy policy at humanservices.gov.au/privacy

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information by the Department of Human Services (DHS) to the Queensland Cerebral Palsy Rehabilitation and Research Centre, the University of Queensland, for the purposes of the Predict CP Study

Important Information (This form is only to be used for participants over 14 years of age)
Complete this form to request the release of your personal Medicare claims information and/or PBS claims information to the Predict CP Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

Rights and Privacy:
I understand that:
☐ my MBS and/or PBS information will be disclosed by DHS for the purposes of the study.
☐ the results of this research may be published in articles or journals.
☐ my real name will never be disclosed by DHS, used in the study or published.
☐ my participation in the study is completely voluntary.
☐ I can withdraw my participation in the study at any time.

Consent:
☐ I understand the information provided to me about the study I am participating in.
☐ I have been given the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.
☐ I consent to the disclosure by DHS of my MBS and/or PBS information to researchers for the purposes of the study.

PARTICIPANT DETAILS
1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: ___ /____/_____
DD / MM / YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION
4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☐ Medicare & PBS claims history

for the period* ___ /____ /_____ to: ___ /___ /_____ to the Predict CP Study.
DD / MM / YYYY DD / MM / YYYY

*Note: As the Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.

DECLARATION
I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: ___ /____/_____ **OR**
DD / MM / YYYY

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: ___ /____ /_____
DD / MM / YYYY

☐ Legal guardian** ☐ Power of attorney** ☐ Guardianship order**

* Once a young person has turned 14 years old, they must consent to their own information being released
** Please attach supporting evidence

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type	Hospital Indicator	Item Category
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash	N	1
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill	N	2

A sample of the information that may be included in your PBS claims history:

Date of supply	PBS item code	Item description	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	ATC Code	ATC Name
06/03/09	03133X	Oxazepham Tablet 30 mg	$5.30	$25.55	N05 B A 04	Oxazepam
04/07/09	03161J	Diazepam Tablet 2 mg	$30.85		N05 B A 01	Diazepam

** Under co-payments can now be provided for data after 1 July 2012

APP 5 – PRIVACY NOTICE

Your personal information is protected by law (including the Privacy Act 1988) and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services.

Your information may be used by the department, or given to other parties where you have agreed to that, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

You can get more information about the way in which the department will manage your personal information, including our privacy policy at humanservices.gov.au/

PARTICIPANT WITHDRAWAL OF CONSENT FORM

Predict CP: Implementation of Comprehensive Surveillance to Predict Outcomes from Children with Cerebral Palsy

I hereby wish to WITHDRAW my consent to the Predict CP Study. The effective date of this notification is the date inserted below.

I wish to withdraw:

☐ from the overall study and have no further participation.

☐ all MBS and PBS claims information collected prior to my withdrawal date.

☐ from the study but still allow the MBS and PBS claims information collected so far to be used in the study.

I understand:

☐ that all data already collected that has been analysed and/or published cannot be destroyed.

☐ that this will not affect my relationship with my general practice or the Department of Human Services and will have no bearing on the medical care I receive.

☐ I have been informed of the implications of withdrawal from the research project.

…….. ……

Signature **Date**

……..……

Please print full name

If revoking your consent to participate, this page should be forwarded to:

Professor Roslyn Boyd
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