Parent Information Leaflet

Early Detection and Intervention for Cerebral Palsy in Ireland

INTRODUCTION

You are being invited to take part in a research study led by **Prof Brian Walsh, in the INFANT Research Centre** at University College Cork and Cork University Maternity Hospital. Before you decide whether to take part it is important for you to understand why we are doing this research and what is involved. Please take time to read this leaflet, and if you want to, discuss it with your doctor, midwives, family, or friends. Please feel free to ask us if anything is not clear, or if you would like more information. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you and your baby. This process is known as 'Informed Consent'.

A copy of this Patient Information Leaflet and the associated Data Protection Notice will always be available on the INFANT website: www.infant.ie/research/edi-cpi.

ABOUT THE STUDY

Cerebral palsy (CP) is a condition when a baby or a child has a brain injury that affects their movement and muscle tone. Some people with CP can have other developmental issues, like learning impairments, but many do not and have isolated issues with their motor skills. Some newborns are at higher risk of developing CP, including babies born premature, those who have an injury to their brain, and those who have an abnormal neurological exam. However, most babies with a higher risk of CP do not develop CP. The problem is that clinicians can't tell at the start who will and who will not develop CP, we can only say who has a risk of it. Therefore, we follow these babies up in out-patient clinics to see how they are progressing. These babies are usually followed by a neonatologist (baby doctor), often a physiotherapist, and may also be referred to services in the community like the Early Intervention team. If there is a significant concern, doctors will often perform a scan of their brain to provide more information. Even with all this follow-up it still usually takes at least 2 years to diagnose a child as having CP.

In this study we want to try and reduce the age of diagnosis of CP by assessing children in high risk out-patient clinics using specific clinical exams that have been shown to be more accurate in predicting CP. This study is being conducted at several hospitals across Ireland, including Cork University Maternity Hospital, The Rotunda Hospital, The National Maternity Hospital, Coombe Women and Infants Hospital, and University Maternity Hospital Limerick. It is being coordinated by the In4kids network and will run through the INFANT centre and University College Cork. The study has been funded by the Cerebral Palsy Foundation, USA.

A similar project was conducted in the USA and showed that using these specific clinical exams at set times, they could reduce the average age of CP diagnosis by 10 months. We hope that we can achieve something similar and show that in Ireland we can reduce the age of CP diagnosis by using these proven clinical exams.

WHY HAVE MY BABY AND I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part because your baby is thought to be at a higher risk of having had a neurological injury, and because of this is due to be followed up in neonatal or paediatric out-patients. There are many reasons why a baby might be considered at higher risk, the most common reasons are that they are born premature or have an abnormal neurological exam before they are discharged. It is important to remember that most babies considered at risk, do well and do not have any significant injury.

DO I HAVE TO TAKE PART?

You don't have to take part in this study. If you decide not to take part, it won't affect your or your baby's current or future medical care. You can change your mind about taking part in this study any time you like. Even if the study has started, you can still opt out. You don't have to give a reason. If you do opt out, it won't affect the quality of the medical care you or your baby get now or in the future.

HOW WILL THE STUDY TAKE PLACE?

Approximately 1500 babies will take part in this study across Ireland- with babies being enrolled from Cork University Maternity Hospital, The Rotunda Hospital, The National Maternity Hospital, Coombe Women and Infants Hospital, and University Maternity Hospital Limerick, over a three year period. If you choose for your baby to participate, it will require you to attend 3 to 5 out-patient visits in Cork over a two year period. At the out-patient visits your child would be assessed by a doctor and/or a physiotherapist. We may also ask you to fill out a questionnaire for your feedback on the process, to see if we can improve how we communicate with families.

WHAT WILL THE STUDY INVOLVE?

All babies will be reviewed before going home, then asked to attend 3 out-patient clinics; at 3-4 months, 9-12 months, and 24-26 months after their due date (Table 1 provides an over-view of the appointments).

We plan to use a few different standardised assessments to try and improve the diagnosis of CP. These assessments include the following;

- The first assessment, called the Prechtl General movements assessment, requires observing your baby while they are awake and quiet. To do this we will take a short two minute video of your baby and up-oad it to a secure database so that we can assess your babies movements while they are quiet. We will take a video at least once before your baby is discharged from the neonatal unit, and once when your baby is 3-4 months of age.
- This video will be uploaded and stored using a secure online research database called Research Electronic Data Capture (REDCap) which is hosted by UCC. If you chose to take the video yourself at home when your baby is 3-4 months of age instead of coming into outpatients, you will receive a link from this database to your email which will look like a survey – this is where you will upload the video.

- The video will be completely deleted when all data related to the study has been collected and checked to be accurate – this is usually called Database Lock and occurs approximately 12 months after the study is completed.
- The other assessments that we would like to perform include a standardized neurological exam (called the Hamersmith Infant Neurological Exam[HINE]), and a standardized assessment of your babies motor skills [how they move]. These assessments will be performed by a physiotherapist. The motor assessment will be performed once at 3-4 months of age, and again at 9-12 months of age, and takes about 20 minutes. The HINE will be performed at each out-patient review, and takes about 10 minutes to perform. Neither assessment will cause any hurt or discomfort to your baby.
- At each appointment your baby will also be seen by a doctor to perform a quick medical history and assessment (just to see how things are progressing since we last saw you).
- Every baby when they are about 2 years old will also have a full developmental assessment, looking at their movement, language, and learning skills. This is called the Bayley Scales of Infant Development. It will be performed by a clinician trained to perform it. During this assessment you will be asked specific questions about your child's development Your child will be asked to demonstrate certain skills, such as seeing how they run, use a ball, play with blocks and other toys, to name a few things. It takes about 45 minutes to perform this assessment.

Additional Assessments performed for those Likely or Confirmed to have CP

If there is a concern that your baby may be showing signs of CP we will ask to perform some additional tests. Although this may be worrying for you, please be assured that we will explain in detail the reasons for deciding to do them and what they involve. A neonatologist / doctor will be available to discuss your concerns about these assessments and of a potential diagnosis of CP. We strongly encourage you to use this support as they will be able to guide you appropriately with accurate and up to date information. We will work with you and your doctor (if necessary) to ensure you have all the support you need and will refer you to any relevant help groups should you so desire.

Specifically we may conduct an additional review at 6 months. At this review the HINE will be performed again and an additional review with a doctor will occur. This is because if a baby is showing concerning signs, we do not want to wait 6 months between appointments but wish to review them sooner.

In addition if there is concern that the assesments performed (Prechtl and HINE) indicate a high risk of CP, these results will be discussed with the clinical team looking after your baby, and it may be decided to perform an MRI. An MRI is a method of taking images of your baby's brain and takes approximately 40 minutes to perform. Younger babies can often be fed right before the scan, and then swaddled and will sleep straight through it. Older infants will often need sedation. An MRI brain is often performed in children with a high concern for CP to confirm the diagnosis. This will be conducted in agreement with you and the clinical team caring for your baby, and they will have the results available to them to help with whatever clinical care is required based upon the results.

If your child is found to have CP, we will perform additional assessments of their motor function at their 24-26 month appointment(the Peabody Developmental Motor Scale, and Gross Motor Function Measure). These are performed by physiotherapists on children with CP, and can provide information on a child's response to therapy over time.

Lastly if your child is found to have CP we will ask you to complete a short questionnaire on your impression of how we discussed the diagnosis with you. We are doing this as we want to make sure we are aware of parents feelings, and receive their feedback, so we can improve our communication and try to help families as best we can.

A copy of the signed informed consent form will be given to you for your records and a copy will be scanned and included in your baby's medical notes.

BENEFITS, RISKS and SAFETY

Your baby will benefit from having detailed developmental follow-up appointments in a high-risk clinic to assess their progress. At these appointments they will be assessed using specific exams that are proven to help diagnose CP. Although these assessments (Prechtl and HINE) are evidence based, and currently used clinically in many locations across Europe and North America, they are not currently routinely performed in our clinical OPD as there is often not enough trained staff available to perform them. The results of these assessments will be made available to the clinical team caring for your child, to ensure that any additional information gathered is used to optimise their care.

There are no risks that we know of. This is an observational study and does not involve intervention on the patient. Therefore, the participation will not result in particular risks. Furthermore, if you are being asked to be involved in this study, then your child would already routinely be followed in a high-risk follow-up clinic in either Cork or your referring hospital. The difference in this study, is that in a routine out-patient clinic it is up to the individual clinician to decide how often to see a child, how long to follow them, and what assessments to perform when they are seen. Therefore it is quite variable. If you are scheduled to have follow-up in your referring hospital, rather than in Cork, we will ask that in addition to your routine local follow-up, you also attend a Paediatric clinic in Cork to complete these standardised assessments.

INSURANCE

University College Cork as the Sponsor of this research study has appropriate insurance in place if you / your child is harmed because of participation in this study. If you / your child is harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the hospital where you / your child is being treated. The normal Health Service Executive complaints mechanisms will be available to you if appropriate.

WHAT WILL HAPPEN TO THE RESULTS OF THIS RESEARCH?

Results of this research study may be published in medical journals and presented at scientific meetings. However, you will never be identified individually during these presentations and will not be revealed in any reports or publications. Your name or anything else identifiable to you will not be released or published.

FUTURE USE OF DATA COLLECTED

We would like to use the data collected as part of this study for future related research studies without your further consent. Related studies mean studies looking at Cerebral Palsy and/or neurodevelopmental outcomes. The assessments performed in this study mainly are about understanding neurodevelopmental outcomes, and by this we mean a childs developmental milestones such as the age that a child gains certain skills like walking, or talking.. Any further study would have approval from a Research Ethics Committee before your data could be used. You can indicate in the consent form attached to this leaflet whether you consent or not to the data being used in future related research studies.

WHO HAS REVIEWED THIS STUDY?

All research in Ireland is carefully reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing, and dignity. This study has been approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals.

WHAT WILL HAPPEN IF I DO NOT WISH TO CARRY ON IN THIS STUDY?

You are free to withdraw at any time, without giving a reason. This will not affect the high level of care you will expect for yourself. If you would like to withdraw, please contact any member of the study team. We would however like your permission to use the information that has already been collected up to the point of withdrawal. You have the right to request

the deletion of data about you or your child if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing (please see Data Protection Notice for further information).

WHERE CAN I GET MORE INFORMATION?

The study will be fully explained to you and any questions answered before you decide if you want to take part. If you have any further questions regarding this study, please contact the Principal Investigator: Prof Brian Walsh, Dept of Neonatology, Cork University Maternity Hospital. Tel: 0214920525.

Table 1. Planned Visit and Assessment Schedule

Visit	Before Going Home (NICU)	3-4 month (OPD)	Possible 6 month * OPD)	9-12 month (OPD)	24-26 month (OPD)
Assessment					
GMA (short video)	x	x			
HINE		x	x	x	x
Motor Assessment		x			
Medical and history	x	x	x	x	x
BSID					x
Possible Additional Assessments					
MRI*	+/-	+/-			+/-
PDMS/GMFM†					+/-
Parental Questionnaire on communication†					+/-

GMA- General Movements, HINE- Hammersmith Infant Neurologic Evaluation, PDMS- Peabody Developmental Motor Scale, GMFM- Gross Motor Function Measure, BSID- Bayley Scale of Infant Development

*6 month visits and MRI is not standard, but should be provided to infants thought to be higher risk based on assessments, † Only performed **if** there is a diagnosis of CP made.

DATA PROTECTION NOTICE

Any personal data which you provide to the study will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This notice sets out details of the information that we collect, how we process it and who we share it with. It also explains your rights under data protection law in relation to our processing of your data.

This Data Protection Notice and any subsequent changes will be available through the INFANT Website (www.infant.ie/research/edi-cpi).

WHO WE ARE

The Data Controllers for this study are Universitiy College Cork, Royal College of Surgeons of Ireland and the National Maternity Hospital. As this study begins in the other sites, they may be added as joint data controllers. Throughout this Notice, “we”, “us” and “our” refers to University College Cork, as study sponsor of Cork study and Royal College of Surgeons of Ireland and the National Maternity Hospital, as Joint Data Controller. For more information about us, please refer to our website https://www.ucc.ie/en.

HOW WE WILL USE YOUR PERSONAL DATA

By participating in this study, information about you (also called “personal data”) will be accessed, collected and stored for the purposes mentioned in the Participant Information Leaflet relating to the study. This personal data includes

- Information that directly identifies you (such as your name and your year of birth);
- Your gender, ethnic and racial background;
- Information on your health and medical condition including your medical history;
- Your treatments and your response to treatments;
- Information from your medical records

Personal data collected at any time during the study will be kept strictly confidential. The data will be held securely in the INFANT Centre which is hosted in UCC and referred to in this notice as "the clinical site". To ensure confidentiality, the data generated during the study is coded with a number that will identify you in the study. Any information that leaves the clinical site will be labelled with your code instead of your name. Every person that has access to your uncoded data at the clinical site is subject to professional secrecy and confidentiality.

Data that directly identifies you (uncoded data) is stored in your medical files at the clinical site. A list or 'key' linking your study number to your name will also be kept securely on a secure encrypted file with restricted access by the researcher(s).

WHO WILL ACCESS MY PERSONAL DATA?

Your uncoded data will only be accessible to clinical site employees, the study researcher(s) and site staff, quality representatives from the study Sponsor (Monitors and Auditors), and the Clinical Research Ethics Committee of the Cork Teaching Hospitals so that they can check if the study is being conducted to the best standards.

Results of the study will be provided to the ethics committee approving the study in compliance with national and international regulations on clinical studies.

THE PURPOSE AND LEGAL BASIS FOR COLLECTING YOUR DATA

Any personal data you provide to us during this study will be processed fairly and lawfully. Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in this Patient/Participant/Parent information leaflet (PIL). You are entitled to withdraw your consent at any time.

Personal data collected during this study and the results of the study may be presented for scientific purposes. However, you will never be identified individually during these presentations. Your identity will not be revealed in any reports or publications.

The clinical site staff, the study researcher and the members of the study's team will use your personal data within the scope defined above. If the clinical site staff, study researcher or study team wish to use your data for a purpose other the purpose specified, the researcher must contact you again to give you more information and ask your permission to use your data for the new purpose.

The General Data Protection Regulation (GDPR) allows us to process your data because the research is of substantial public interest (Articles 6(1) (e) and 9(2) (j) of the GDPR). If you require further information on the legal basis for processing your personal data, please contact University College Cork Data Protection Officer - details below.

HOW LONG WE WILL KEEP YOUR DATA

The personal data collected in the study will be kept for a period of 10 years as per University College Cork Code of Research Conduct v2.4 dated 14 SEP 2021 after the end of the study. Thereafter, they may be stored for a further period of time for legal reasons (e.g. revised retention obligations), or more if required by law.

YOUR RIGHTS

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- to have inaccurate/incomplete information corrected and updated;
- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data by University College Cork;
- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form);

- to withdraw your consent to the processing of your data at any time without giving a reason by notifying your decision to the study researcher. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study Researcher will present you the options you have concerning your personal data.
- If, for any reason, you stop attending the study visits, your study Researcher may decide to withdraw you from the study. If this happens, we will continue to hold your data for research purposes unless you inform us that you do not want us to hold your data any longer.
- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing.

If you wish to exercise any of these rights, please address your request to the study researcher or the Data Protection Officer, University College Cork (details below).

QUESTIONS OR COMPLAINTS

If you have any questions in relation to this study, please contact the study researcher or a member of the study team on 0214920525

If you have any complaints in connection with our processing of your personal data, you can contact University College Cork Data Protection Officer (DPO):

Office of Corporate & Legal Affairs,
University College Cork,
Western Road, Cork.
E: gdpr@ucc.ie; T: 021 490 3949

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

PARTICIPANT INFORMED CONSENT FORM

Early Detection and Intervention for Cerebral Palsy in Ireland

Participant MRN: _____	**Chief Investigator:** Dr Brian Walsh
Participant DOB: _____	**Contact details:** Dept of Neonatology,
Study Number: _____	Cork University
	Maternity Hospital
	Tel: 0214920525

Please initial YES in each section to show you have read understood, and agree to the statement.

If you agree to take part, please sign the bottom of the form.

	Please initial	
	YES	**NO**
1. I have read the information leaflet about this study and have been given a copy to keep. The information has been fully explained to me and I have been able to ask questions and have them answered satisfactorily. I understand why the research is being done and any risks involved.		
2. I am aware that my child's participation is voluntary, and I may withdraw consent at any time. I am aware that my decision not to continue participation at any stage will not restrict my access to health care services normally available to me and my child**.**		
3. If I withdraw from the study, I may request that my child's data is deleted. I understand it may not always be possible to delete coded personal data (already collected) to preserve the integrity of the study.		
4. I am aware that confidentiality of records concerning my child's involvement in this study will be maintained according to national and EU Data Protection Laws. When required by law, the records of this study may be reviewed by government agencies, ethics committee and sponsors of the study.		
5. I understand that the sponsors and Investigators have such insurance as is required by law in the event of injury resulting from this research.		
6. I agree that I can be contacted in the future in relation to this research study		
7. I agree that I can be contacted in the future in relation to other research studies		

	Please initial	
	YES	**NO**
8. I give permission for the information collected from me about my child to be stored for possible future commercial or collaborative research related to the current study (i.e. Cerebral Palsy and / or Neurological outcomes) *without my further consent being required* but subject to approval of a Research Ethics Committee.		
9. I consent that data collected for this study may be used, now or in the future, and understand that I will not benefit financially if this research leads to the development of a new treatment, drug, or device.		
10. I give permission for my child's medical records to be reviewed and information to be taken from them to be analysed in confidence by the study team.		
11. I agree that anonymised data, clinical assessments, videos of exams, and MRI scans obtained during this study, can be used for training and research purposes.		
12. I understand that if the study team have any concerns regarding the health of my child, they may contact me or our GP/hospital doctor.		
13. If I have further queries concerning my rights in connection with the research, I can contact the the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, Little Hanover Street, Cork (Tel 021 4901901).		

Parent / Legal Representative Signature:	Date:	Time: Circle AM/PM
Parent / Legal Representative Signature:	Date:	Time: Circle AM/PM
Consent obtained by: Researcher's Signature	Date:	Time: Circle AM/PM

INFORMED CONSENT FORM FOR MATERNAL DATA COLLECTION

Please initial YES each section to show you have read, understood and agreed to each statement. If you agree to take part, please sign the bottom of the form.

	Please initial	
	Yes	**No**
1. I have read the information leaflet about this study and have been given a copy to keep. The information has been fully explained to me and I have been able to ask questions and have them answered satisfactorily. I understand why the research is being done and any risks involved.		
2. I am aware that my participation is voluntary, and I may withdraw consent at any time. I am aware that my decision not to continue participation at any stage will not restrict my access to health care services normally available to me.		
3. If I withdraw from the study, I may request that my data is deleted. I understand it may not always be possible to delete coded personal data (already collected) to preserve the integrity of the study.		
4. I give permission for my medical records to be reviewed and information to be taken from them to be analysed in confidence by the study team.		
5. I am aware that confidentiality of records concerning my involvement in this study will be maintained according to national and EU Data Protection Laws. When required by law, the records of this study may be reviewed by government agencies, ethics committee and sponsors of the study.		
6. I understand that if the study team have any concerns regarding my health, they may contact me or our GP/hospital doctor.		
7. I agree that I can be contacted in the future in relation to this study.		
8. I agree that I can be contacted in the future in relation to other research studies		

Maternal Signature:	Date:	Time: Circle AM/PM
Consent obtained by: Researcher's Signature	Date:	Time: Circle AM/PM