Parent Information Leaflet (Case Group)

AIM-HIGH:

Assessing Intellectual and Motor outcomes in High-Risk infants

INTRODUCTION

You and your child are being invited to take part in a research study in the INFANT Research Centre at University College Cork and Cork University Maternity Hospital (CUMH). 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.

If you would prefer to view this Parent Information Leaflet in video format, please scan the QR code below.

You should clearly understand the benefits and risks of taking part in this study as detailed in this leaflet so that you can make a decision that is right for you and your child. This process is known as 'Informed Consent'. If anything is unclear, or if you would like more information, please feel free to ask any questions – we will be happy to answer them. Once you understand it fully, you will be asked to sign the consent form if you are happy for you and your child to take part. A copy of this information leaflet will be given to you to keep. Thank you for taking the time to read this.

ABOUT THE STUDY

We know that events that happen around the time of birth can increase the risk of difficulties in growth and development of a child. Premature delivery, or brain dysfunction or seizures in the newborn baby (also called "neonatal encephalopathy") can lead to an increased risk of difficulties in the future. These difficulties can be in movement (such as Cerebral palsy or CP), difficulties in learning (cognitive delay), or loss of hearing or vision. However, most babies with a higher risk do not develop these difficulties. The problem is, at early stages, doctors are unable to tell who will and who will not develop difficulties, such as CP, they can only say who has a risk of it. Therefore, these babies are followed up in out-patient clinics to see how they are progressing, usually by a neonatologist (baby doctor), often a physiotherapist, and some 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 the baby's brain to provide more information.

In this study the aim is to try to improve prediction of later motor or cognitive difficulties by assessing children in high risk out-patient clinics using novel and specific clinical examinations that may be more accurate in predicting later difficulties in movement, speech, learning, or vision. This study is being conducted at several hospitals in Ireland, including Cork University Maternity Hospital (CUMH), The Rotunda Hospital and the Coombe Women and Infants Hospital. It is being coordinated by the In4kids network, INFANT centre/ University College Cork (UCC).

STUDY FUNDERS

The study has been funded by Science Foundation Ireland (SFI) and the Cerebral Palsy Foundation, USA.

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

You are being asked to take part because your child is thought to be at a higher risk of later difficulties, and because of this is due to be followed up in neonatal or paediatric out-patient clinics. There are many reasons why a child 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?

The decision to take part is completely up to you; you are under no obligation to participate. Your decision not to participate will not affect the medical care of you or your child at any point. We are very grateful to you for considering your and your child's participation, but we understand if you decide not to enrol. If you do decide to take part, you will be asked to sign the consent form at the end of this information leaflet. You will be given a copy to keep. If you decide to take part initially and then change your mind, you are free to withdraw yourself and your child from the study at any stage without giving any reason.

If you wish to withdraw from the study, you can do so by contacting the Principal Investigator – contact details outlined below. No further information will be collected about you or your child. However, it may not be possible to remove the information that has already been collected about you and your child as this could affect the research results or because it may not be possible to identify your information if the data has already been anonymised.

WHAT WILL THE STUDY INVOLVE?

Approximately 600 babies will take part in this study in Ireland over a two-year period. If you choose for you and your child to participate, it will require you to attend 5 out-patient visits in CUMH &/or INFANT research centre in CUH over the next 2 and a half years.
Your child will be reviewed before being discharged from the maternity hospital. They will have a measurement of their brain wave activity in the neonatal unit and will have small amounts of blood stored for the measurement of brain related proteins. They will have the standard assessment of their movement and muscle tone. Following discharge there will be 5 out-patient clinics to attend at the following times; approximately 4 months, 9 months, 18 months, 24 months and 30 months. At the out-patient/ INFANT visits, your child will be assessed by a physiotherapist and/or a doctor. At each time the research team will carry out detailed assessments of your baby's growth and development. They will be focused on looking for early signs of developmental delay, movement disability (cerebral palsy) or learning delay. These assessments will include standard assessments and also new assessments developed in the INFANT centre such as measuring early brain activity during sleep, early eye tracking and observing the baby's movements and interactions at an early stage to predict outcome at 2.5 years of age. Detailed information on each of the assessments can be found at the end of this leaflet.

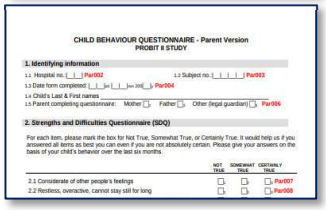
Table 1: AIM-HIGH Assessments per Planned Visits

CORRECTED GESTATIONAL AGE	NICU	15 – 19 WEEKS	9 – 12 MONTHS	18 ± 1 MONTHS	24 ± 3 MONTHS	30 + 1 MONTHS
ASSESSMENTS	VISIT 1	VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6
Medical and History	x^					
Neuro-specific proteins	x					
MRI	x*					
ROP Screening	x*					
EEG	x	x^				
HINE		x^				
Sleep Diary & Interactive Questionnaire		x^				
Spontaneous Interaction		x^				
VEP		x^				
Early gaze fixation		x^				
Edinburgh Postnatal Depression Questionnaire		x^				
CVI assessment			x*			
Parent Perspective Questionnaire			x~			
Bayley's Scales of Infant and Toddler Development IV			x^		x^	
Griffiths III				x^		
Visual Acuity			x^	x^	x** ^	
Novel Eye-tracking			x^	x^		
CogniTOT ET task				x^	x^	
Peabody Development Motor Scales					x#	
Child Behavioural Checklist					x^	
WPPSI – III						x^

** Only as clinically indicated, ** To conduct on infants that failed 18-month VA screening and/or returning with refractive correction or concerns, ^ Case and Control cohort, x Control infants only ~ Case infants only*

 # To be conducted on infants diagnosed with CP only.

VISIT 1: During NICU Stay		
		
▪ Blood Sample Stored (if obtained)	▪ EEG	▪ General Movements
VISIT 2: 4 months		
		
▪ Early Eye Gaze (if possible)	▪ EEG ▪ Vision Test (VEP)	▪ Postnatal Depression Questionnaire ▪ Return Sleep Questionnaire
VISIT 3: 9 -12 months		
		
▪ Vision and Eye Tracking (if possible)	▪ Cognitive & developmental assessments ▪ Parental Perspective Questionnaire	
VISIT 4: 18 months		
		
▪ Vision and Eye Tracking (if possible)	▪ Cognitive Behavioral & Developmental assessments	

VISIT 5: 24 months
  CHILD BEHAVIOUR QUESTIONNAIRE - Parent Version PROBIT II STUDY 1. Identifying information 1.1 Hospital no. [ ] Par002 1.2 Subject no. [ ] Par003 1.3 Date form completed: [ ] Par004 1.4 Child's Last & First names 1.5 Parent completing questionnaire: Mother Father Other (legal guardian) Par006 2. Strengths and Difficulties Questionnaire (SDQ) For each item, please mark the box for Not True, Somewhat True, or Certainly True. It would help us if you answered all items as best you can even if you are not absolutely certain. Please give your answers on the basis of your child's behavior over the last six months. NOT TRUE SOMEWHAT TRUE CERTAINLY TRUE 2.1 Considerate of other people's feelings Par007 2.2 Restless, overactive, cannot stay still for long Par008	▪ Cognitive Behavioral & Developmental assessments
VISIT 6: 30 months
	▪ Detailed Developmental assessment

BENEFITS, RISKS and SAFETY

Your child will benefit from having detailed and regular developmental follow-up appointments and access to referral pathways if required (eg: vision).

There are no risks that we know of as this is an observational study and does not involve intervention on the patient. If you are being asked for your child to be involved in this study, your child would already routinely be followed in a high-risk follow-up clinic in either CUMH 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. This study is well structured, with defined tests at defined times over 30 months (see Table 1).

INSURANCE

University College Cork is the Sponsor of this research study for all sites (Cork and Dublin) and has appropriate insurance in place if you/your child is harmed because of participation in this study. If you or 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 or your child will never be identified individually during these presentations and will not be revealed in any reports or publications. Your or your child's name or anything else identifiable to you or your child will not be released or published.

FUTURE USE OF DATA COLLECTED

We would like to use the anonymised 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 are mainly about understanding neurodevelopmental outcomes, and by this we mean a child's 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 anonymised data could be used.

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 and your child. 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 Deirdre Murray, INFANT Centre, Cork University Hospital. Email: deirdre.murray2@hse.ie

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 and your child's data.

DATA CONTROLLERS

The Data Controllers for this study are University College Cork (UCC) and the Royal College of Surgeons of Ireland (RCSI). 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 UCC, as study sponsor for all recruiting sites (Cork and Dublin) and RCSI as Joint Data Controllers. 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 and your child (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 and your child's health and medical condition including your medical history;

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, your name or your child's name will not be used. Instead, the data generated during the study is coded with a number that will identify your child in the study. Any information that leaves the clinical site will be labelled with this code instead of your child's name. Every person that has access to your child's uncoded data at the clinical site is subject to professional secrecy and confidentiality.

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

WHO WILL ACCESS MY PERSONAL DATA?

Your child's uncoded data will only be accessible to clinical site employees, the study researcher(s) and site staff, quality representatives from the study Sponsor (UCC) including 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 and your child's personal data will be used for the purposes outlined in this 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 or your child will never be identified individually during these presentations. Your or your child's identity will not be revealed in any reports or publications. An anonymised dataset from which you cannot be identified may be uploaded to an open source data repository to support the published results.

The clinical site staff, the study researcher and the members of the study's team will use your and your child's 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.

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 and your child's personal data, access your and your child's personal data and receive copies of your and your child's personal data;
- to have inaccurate/incomplete information corrected and update

- in certain circumstances, to have your and your child's details deleted from systems that we use to process your and your child's personal data or have the use of your and your child's personal data restricted in certain ways;

- to object to certain processing of your and your child's 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 and your child's 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 and your child's participation in the study stops and no further data will be collected from you or your child. Your study Researcher will present you the options you have concerning your and your child's 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 and your child's data for research purposes unless you inform us that you do not want us to hold your and your child's data any longer.
- Along with study withdrawal, you have the right to request the deletion of data about you and 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.

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 please contact the Principal Investigator: Prof Deirdre Murray, INFANT Centre, Cork University Hospital.
Email: deirdre.murray2@hse.ie or a member of the study team on
Tel: TBC

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.

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.

FOR HOW LONG WILL THIS DATA BE KEPT?

We will keep identifiable information about you and your child from this study for a period of 10 years after the study has concluded, as per UCC Code of Research Conduct document. The data will be stored securely at the INFANT Centre, UCC. A pseudonymised database (where participants are assigned unique numbers and there is no identifiable information) will be stored on researcher's password protected encrypted computers at UCC. All information management will adhere to the Data Protection Act and GDPR. 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. We would like your permission to allow us to store your child's anonymised data for future related research as outlined above for a further period of 15 years once the master key linking you and your baby to your identifiable data has been destroyed after 10 years. Further research analyses may be performed but this will be subject to further ethics approval if applicable.

DETAILED LIST OF ASSESSMENTS AND VISITS

At each appointment your child will be seen by a member of the study team who will check to see how things are progressing since we last saw you.

Blood samples:

Blood microsampling is a method used to collect and analyse very small volumes of blood. A small prick to the skin / heel or fingertip is required to draw small amounts of blood in a quick and minimally invasive manner. Blood microsampling will take place at the same time as the blood tests which your child needs as part of their routine care. This will therefore not require any extra needles. All obtained blood samples will be tested to see if there are any special proteins present in the blood that could help us identify babies with or at risk of

brain injury earlier. In total we will take less than 1ml of blood in preterm infants and around 2mls of blood in full term infants (less than half a teaspoon).

EEG:

An EEG (electroencephalogram) is another assessment that will be conducted. This is a video recording of your child's brain activity while they sleep as a newborn and at 4 months of age. To capture the recording, soft pad sensors will be applied to your child's head. This is a painless procedure and will not distress your child. Similar to older children and adults, babies have different types of sleep, both dreaming sleep with rapid eye movements (REM) and non-REM sleep. Babies move between the two different types of sleep with a complete cycle of both REM and non-REM lasting 1 hour. For the EEG test at approximately 4 months of age, we aim to capture 1-2 sleep cycles if possible. For this test, we will decide with you the best time to capture sleep in your child (usually after a feed). This EEG is for research purposes only and does not replace a full clinical EEG which may be ordered by a consultant paediatrician to investigate medical issues should they arise.

Visual Evoked Potentials (VEP):

A VEP scan assesses the health of the vision system by recording how the eyes respond to a flash of light or checkerboard image. The test uses the same soft pad sensor set-up as the EEG and runs either before or straight after the EEG recording during Visit 2. This is a

painless procedure and will not distress your child. The test will take approximately 10 minutes to complete and will be conducted by trained investigators only. If any delay in the brains response to light is detected, we will arrange for your baby to be formally assessed by an eye specialist.

Sleep and Interaction Diary:

You will be asked to track your child's sleep patterns for the first 4 months of life. You will also be asked to record your interactions with your child one day a week over the same period. You can decide between a paper-based, handwritten diary where you shade out the times that your child slept every 24 hours and write/tick boxes beside interaction activities

in a table, or you can download an online Infant Sleep app for ease. You will hand back the diary at Visit 2.

Spontaneous parent – infant interactions:

You will be asked to interact as you would normally do with your baby for 3 minutes, chatting and smiling as usual as we observe their reactions. The interaction will be recorded using a video camera. Your child will be placed on a nursing pillow on the floor, with you sitting directly opposite. We encourage you to engage with your child as you would normally, without the use of toys or a pacifier. This interaction will take place in a quiet room, in between feeding times when your infant is calm.

Early Gaze Fixation:

We will also look at early social interactions (eg: smiling) and eye-control during Visit 2. The researcher will present a moving object in front of your child and record their interactions and their eye-movements using a video recording device positioned on the researcher's head. This test will take approximately 5 minutes to conduct.

Vision and Eye Tracking:

We will examine your child's interactions in more detail when they are 9 months and/or 18 months of age while seated in front of a computer screen. Different pictures will appear on the screen, and recordings of how well your child moves their eyes and/or stays focused on

these different images will be conducted. The test will take approximately 30 minutes to complete. We will also assess your child's vision during these visits.

Cognitive Tests:

We are interested in measuring how well your child thinks, understands, and processes information. These will be done at age 9 months, 18 months, 24 months and 30 months using age appropriate standardised assessments used by child psychologists, and also a newer test using a tablet based application developed in the INFANT Centre. At each time point it will take approximately 30 minutes to complete each of these tests.

Child Behavioural Checklist:

This is a parent-reported questionnaire which we will ask you to complete when your child is 24 months. It will examine whether your child is showing difficulties in behaviour. Behavioural concerns may include hyperactivity, impulsivity, aggression, difficulty sustaining attention, and disruptions to learning and peer relations.

Maternal Edinburgh Postnatal Depression Scale:

Exposure to long term stress can impact your own mental health and engagement. We will ask you to complete a 10-part questionnaire to assess your emotional distress during the postpartum period and provide guidance if required. This will be completed at the 4 month visit.

Parent Perspective Questionnaire (for parents of infants born less than 32 weeks):

This is a unique, 15 question parent reported questionnaire, developed with the help of a Parent Advisory Group. It is designed to explore how information related to your child was delivered to you, and how communication and perinatal counselling can be improved from your perspective. It offers a unique chance to voice your concerns and/or experiences. A link to the questionnaire which is unique to you will be sent to you either by email or by post whichever you prefer, when your child is approximately 12 months corrected age. It is to be completed and returned within one month of receiving it.

Additional Assessments performed for those Likely or Confirmed to have CP

If there is a concern that your child 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 consultant neonatologist or paediatrician will be available to discuss your concerns about these assessments and 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.

An MRI scan of the brain is one possible additional test (as described above) and is often performed on children with a high concern for CP to confirm the diagnosis.

If your child is found to have CP, we will ask to perform one other additional test that assesses their motor function at their 24 – 27-month appointment (the Peabody Developmental Motor Scale). This test is performed by physiotherapists on children with CP and can provide information on how a child will respond to therapy over time.

PARENT INFORMED CONSENT FORM

Study Title: AIM-HIGH: Assessing Intellectual and Motor outcomes in High-Risk Infants

Participant MRN: _____ **Study Number:** _____	**Chief Investigator:** Prof Deirdre Murray **Contact details:** Dept of Paediatrics, Cork University Hospital Tel: TBC Email: deirdre.murray2@hse.ie

Please initial YES in each section to show you have read understood and agree to the statement. If you agree for your child 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 (UCC).		
5. I understand that the sponsors (UCC) 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		
8. I give permission for the anonymised information collected about my child to be stored for possible future commercial or collaborative research related to the current study (i.e. infant and child development) *without my further consent being required* but subject to approval of a Research Ethics Committee.		

	Please initial	
	YES	**NO**
9. I consent that anonymised 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, ROP images 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 FOR MATERNAL DATA COLLECTION

Study Title: AIM-HIGH: Assessing Intellectual and Motor outcomes in High-Risk infants

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

		Please initial	
1.	I have read the attached information leaflet and I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	**Yes**	**No**
2.	I understand that my participation, by allowing collection of data about my pregnancy, labour, and delivery, is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected	**Yes**	**No**
3.	I understand that relevant sections of my medical notes and data collected during the trial, may be looked at by individuals from the Sponsor (UCC), or ethics committees, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my records.	**Yes**	**No**
4.	I give permission for information collected about my pregnancy, labour, and delivery to be stored for possible future research related to this study and that it may be shared anonymously with other researchers without my further consent being required but subject to approval by a Research Ethics Committee.	**Yes**	**No**
5.	I understand that I will not benefit financially if this research leads to the development of a new treatment or medical test	**Yes**	**No**

Mother / Parent: Name: Signature:	Date:	Time: Circle AM/PM
Consent obtained by: Researcher's Name and Signature	Date:	Time: Circle AM/PM