Participant Information Sheet/Consent Form - Parent/Guardian

[Insert site name]

Study Title	*Predicting long-term outcomes of prematurity from early life events*
Short Title	*The BLUEPRINT study*
Protocol Number	*107608 V1.2 2 July 2024*
Project Sponsor	*Murdoch Children's Research Institute*
Co-ordinating Principal Investigator	Professor David Tingay
Site Principal Investigator	*[Site Principal Investigator]*
Location	*[Location TO BE INSERTED]*

Part 1 What does participation involve?

1 Introduction

We are inviting you and your baby to take part in this research study, *the BLUEPRINT study,* because your baby may have been born before 32 weeks' gestation. The research project is aiming to better understand the breathing problems that preterm babies develop after birth. This will help us be better at predicting the types of lung problems that may develop as a baby grows through childhood.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved.

Please read this information carefully. Don't hesitate to ask questions about anything that you don't understand or want to know more about. Before deciding whether or not you want your baby to take part, you might want to consider talking about it with a relative, friend or local doctor. Having a better understanding of what is involved will help you decide if you want your baby to take part in the research.

Participation in this research is voluntary. If you do not wish for your baby to take part, they do not have to. Your baby will continue to receive the best possible care whether or not they take part.

If you decide you want your baby to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to your baby taking part in the research project
- Consent to your baby having the tests and research that are described
- Consent to the use of your baby's personal and health information as described
- Consent to the use of telephone, Telehealth, and alternative digital platforms to discuss the study and, where required, complete study questionnaires.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Most babies born preterm have breathing problems shortly after birth, and many need help with their breathing. Doctors looking after babies take particular care to use the best and most gentle way to help a baby's lungs. However, chronic lung problems still develop for more than half of babies born preterm. The reasons are due to their lungs not being fully grown before birth, and the types of treatments and breathing machines used after birth. This means that whilst the doctors and nurses know which treatments works best for ***most*** babies, they don't know which treatments will work best for ***each*** baby.

The BLUEPRINT Study aims to provide a more precise picture of how a specific preterm baby's lungs are working in the first 7 days after birth. This is called a 'phenotype'. A phenotype is how all the different factors come together to influence a baby's lungs. These factors may be from before and after birth and include the treatments used in the Neonatal Intensive Care Unit (NICU). By understanding the different lung phenotypes that exist in preterm babies, we hope to help doctors know which treatments may be best for a baby and predict which baby might be at more risk for lung problems as they grow up.

The BLUEPRINT study does not involve additional or different treatments for your baby. However, we want to be able to measure how your baby progresses during their time in the NICU and then at 1- and 2-years of age. If your baby is born preterm before 32 weeks' gestation, this project will collect details of the pregnancy and clinical care in the NICU. We will also collect blood (approximately 0.5 mL) on Day 3 and Day 7 after birth and take some pictures of your baby's lungs at regular timepoints during their NICU stay. We will use the blood samples to look at proteins in the blood that could accurately predict different lung phenotypes and chronic lung risks. We will use the lung pictures to look at how the lungs of preterm babies are growing and functioning. We will then use all this information with new computer techniques to map the lung function of each baby during their NICU stay.

3 What does participation in this research involve?

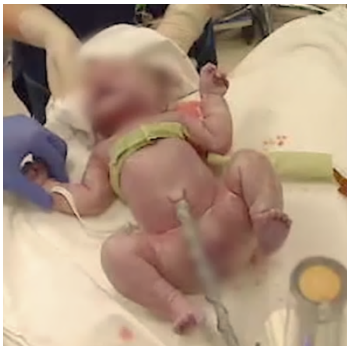
We are interested in understanding what is happening to your baby's lungs during the normal clinical care we provide in the NICU. We will not be changing the care your baby receives in any way. Rather we want to take some additional measurements from your baby during the normal care your baby is receiving.

With your permission we would like to take an additional 0.5mL of blood on day 3 and 7 days after birth (total of 1.0 mL of blood collected throughout the study). We will take blood in the same way that the doctors and nurses do for tests. If the doctors and nurses are taking blood from your baby using a lancet (small needle to take blood from the heel) we will take the 0.5 mL research sample of blood that we need at the same time the doctors and nurses looking after your baby are also taking blood to minimise any additional blood sampling and discomfort for your baby. If the doctors and nurses are taking blood from an arterial line (a small plastic tube in your baby's belly button, wrist or ankle), we will take the 0.5 mL research sample of blood that we need from the arterial line at the same time the doctors and nurses looking after your baby are also taking blood. We will use these blood samples to determine the lung protein profile in your baby's blood (this is called proteomics). We know that different types of lung disease and treatments change the proteins in the lung. This allows us to create a unique molecular 'fingerprint' of your baby's lung. We use proteins as we know that they are a better measure of how the lung is functioning at that time and **do not** involve collecting any genetic information about your baby.

On the same days as the blood samples, we will also take some pictures of your baby's lung using 2 methods: lung ultrasound and electrical impedance tomography (EIT). We have selected lung ultrasound and EIT because they can take pictures of your baby's lungs at the bedside without significantly interfering with your baby and they **do not** use radiation.

Lung ultrasound takes pictures (images) of the different types and severity of disease in the lung, whilst EIT takes images of the air going in and out of your baby's lungs as they breathe. We, and other researchers

around the world, have been using lung ultrasound and EIT for many years to image babies' lungs. We believe both are a very safe way to record a baby's breathing at birth.



Lung ultrasound is similar to the ultrasound used on mothers during pregnancy. A special baby-sized ultrasound probe will be gently placed on each side of your baby's chest using warm ultrasound gel. A trained member of the medical or research team will do the ultrasound. The probe will need to stay in place for 5-10 breaths at each location to take the measurements. The probe is then removed, and the gel gently wiped off your baby's skin.

EIT involves putting a special 1 cm thick EIT belt around your baby's chest. The belt is made of a silk-like material that will not stick to your baby's skin or interfere with breathing (see picture to the left). The EIT belt will be coated with warm ultrasound gel before being gently placed under your baby's back, and gently wrapped around the chest. The process will take 10-20 seconds and sometimes we may have to gently lift your baby slightly off the bed to put the belt on properly.

We will try to place the EIT belt when the medical team are handling your baby for other reasons. We will never place the belt on your baby if the medical team say it is not appropriate to do so. We will then take 4 x 10 minute EIT imaging recordings over the next hour. After the recording period, we will remove the EIT belt the next time a medical team member has to handle your baby for routine medical care. Since EIT can be used to monitor a baby's lungs in the NICU, sometimes we may keep the belt in place during that time if the doctors and nurses want to continue the use the EIT for your baby.

We would also like to take images of your baby's lung with EIT and lung ultrasound at 14 and 28 Days after birth, and when your baby is 36 weeks' post-menstrual age (4 weeks before the expected due date). If practical, we will also try to take pictures on Day 1 and Day 2 after birth.

We are hoping to learn important information about your baby's lungs and if you want, we can give you a copy of the images of your baby's lung.

We will also record information about your baby's health and treatment during their stay in the NICU. There will be no interruption to your baby's care by participating in this study.

After your baby goes home, we would like to assess their lung function, general health, and development when they reach 1- and 2- years of age. These assessments will be performed at the Royal Children's Hospital (Melbourne) to be assessed by a research team member where you will be asked to complete a health questionnaire and additional lung ultrasound and EIT pictures may be taken. At this visit a study doctor or nurse may want to listen to your baby's chest with a stethoscope. This visit will take approximately 1-2 hours. A member of the research team will contact you closer to the follow-up timepoint to organise the appointment for a time that is mutually convenient for you to attend.

By participating in the BLUEPRINT Study, you are giving permission for the co-ordinating study team at the Murdoch Children's Research Institute to contact you closer to your baby turning 1- and 2-years of age, to organise the follow up appointments. The study team at your hospital will ask for the best method of contacting you.

We will reimburse you for some of your out-of-pocket expenses for taking part in this project. We will reimburse you for any reasonable travel, parking, meals, and other expenses associated with the visits at 1- and 2-years of age.

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4 Optional Consent(s)

This research study involves several optional consents. Consent to participate in these optional consents, like the primary consent, is optional. If you do not wish to provide consent for these options, you can still participate in the main study should you wish.

We would like to have your permission to collect information about your race/ethnicity and your postcode to better understand whether either may impact how your baby's lung behave. This information is not always routinely collected across all participating institutions. If you consent to this additional information being collected and it is not already recorded in your baby's medical record, we will ask you to self-report these details.

We would also like permission to use any left-over blood for future testing of emerging blood proteins related to lung injury. Participation in this optional consent, would not require any additional blood draws. The use of any blood samples would be de-identified, meaning any information identifying the blood sample to your baby would be removed and the sample would be labelled using your baby's unique study ID code.

You do not have to agree to any of these optional consents to participate in the study.

5 What do you and your baby have to do?

Babies can join this study if they are born between 22 to 32 weeks of pregnancy. If you agree, your baby will be enrolled in the study from when they are born, or after you give permission (if after birth), until they are about 2 years old.

6 Other relevant information about the research project

This project aims to study 550 preterm babies over 3 years.

This project is being conducted across Victoria and involves the NICUs of the Royal Children's Hospital, Royal Women's Hospital, Monash Health, Mercy Hospital for Women and Joan Kirner Hospital. The Baker Heart and Diabetes Institute will analyse the blood samples.

This research has been initiated by the study doctor, Professor David Tingay at the *Murdoch Children's Research Institute*, Melbourne Australia, and involves study doctors at all the participating NICU sites.

This research is funded by the *National Health and Medical Research Council* (Grant ID 2024039).

The Murdoch Children's Research Institute and The Florey Institute of Neuroscience and Mental Health applied for a provisional patent (#35585449) in September 2023. This patent covers the use of 60 named proteins as a method for early diagnosis and to help to predict the outcomes of infants at risk of developing bronchopulmonary dysplasia. The data collected in the BLUEPRINT study will not contribute to the patent application. However, should the patent be approved, the researchers and the institute could financially benefit from these findings. This may also have future implications for diagnostic tools.

7 Does your baby have to take part in this research project?

No, participation in any research project is voluntary. Your baby does not have to take part if you do not want them to. Even if you decide to have your baby take part, you can still change your mind later, you are free to withdraw them from the project at any stage. You do not need to provide a reason for withdrawing.

If you do decide to have your baby take part, you will be asked to sign this Participant Information and Consent Form and be given a copy to keep.

Your decision whether your baby does or does not take part, or if participation is withdrawn will **not affect** their routine treatment, the care they receive, or the relationship with those treating them and *[Name of Institution]*.

8 What are the alternatives to participation?

Your baby does not have to take part in this research project. If your baby does not participate, they will continue to receive the same care your doctors and nurses think is best for your baby.

9 What are the possible benefits of taking part?

There is no direct benefit to your baby for taking part in this project. We believe this project will provide valuable information about how we care for babies born preterm in the NICU and after they go home. If our new blood tests and tools are successful in detecting lung problems in the early stages of a baby's NICU stay, this will be important in helping improve the care of other babies requiring breathing help in the future.

Our lung imaging equipment is more sophisticated than the equipment we currently have available in the NICU. It is possible we may detect information about your baby that the doctors don't know about. In this case we will immediately tell the team treating your baby.

10 What are the possible risks and disadvantages of taking part?

Participation in this study is not expected to contribute any greater risks to your baby than are possible for any baby that requires NICU care. Procedures for this study, such as lung imaging (EIT and lung ultrasound) will only be performed if the medical team looking after your baby says it is safe to do so. Extra handling of your baby may be required to fit the lung imaging devices, however the medical team looking after your baby will coordinate with normal handling that occurs during the routine care of your baby to minimise disruption or discomfort. There is a possibility that the EIT belt or lung ultrasound procedure may cause irritation, minor damage to the skin or lead to infection however this risk is similar to the risk associated with any medical device that touches the skin. The medical team will take measures, such as using sterile equipment and visually inspecting the skin before and after the procedures to minimise these complications.

The time that you and your baby spend on this research project may be an inconvenience to both. For you, this will include the time to meet with research staff, read this form and consider participation. If participation in the study causes anxiety or other mental health issues for you, we can provide counselling through mental health resources in the NICU. While this research does not involve any interventional treatment, your baby may be receiving other medical treatments that may cause side effects. The study doctor will also be looking out for side effects.

For all large studies like BLUEPRINT, a safety committee is set up to monitor the study. The committee is a group of independent doctors and scientists who have reviewed and agreed to the study. They will monitor the study safety issues at all the hospitals involved. If they find unexpected problems, the study will be stopped or changed to reduce any risks to babies.

There may be side effects that the researchers do not expect or do not know about that may be serious. Tell the study doctor immediately about any new or unusual symptoms.

11 What will happen to your baby's test samples?

You will be asked to provide consent for the collection of your baby's blood during the research project. The 2 blood samples collected from your baby will be processed in the local hospital laboratory and stored for up to 3-months before being transferred to the *Murdoch Children's Research Institute (MCRI)* which is the central site for this study. Your baby's samples will then be sent to the *Baker Heart and Diabetes Institute* to identify proteins that can predict different lung phenotypes and chronic lung risk.

Your baby's samples will be labelled with a unique study ID code that will have been assigned at the beginning of their enrolment in the study. This ID code will not include any personal identifiers such as name, medical record number, date of birth, postcode, or telephone number. Only site study personnel will have access to the master list which links your personal details with your unique ID code; the researchers performing the testing and analysis of your baby's blood samples will not have access to this information.

Any leftover blood samples will be kept at MCRI in a "Biobank" which has been established for the BLUEPRINT study for long-term storage (up to 10 years), perform testing and complete the analysis, after which they will be disposed of as per standard laboratory procedures. During this period, these leftover samples may be used for purposes related to the BLUEPRINT study that are not documented in this consent form. This is called "extended use" where we request extended consent to use these samples for related research only.

12 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available. If this happens, the study doctor will tell you about it and discuss with you whether you want your baby to continue in the research project. If you decide to withdraw your baby, the study doctor will make arrangements for their regular health care to continue. If you decide your baby is to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in your baby's best interests to withdraw from the research project. If this happens, the study doctor will explain the reasons and arrange for your baby's regular health care to continue.

13 Can your baby have other treatments during this research project?

Yes, your baby will continue to receive the care the doctors and nurses consider best for your baby while taking part in this research project.

14 What if your baby is withdrawn from this research project?

If you decide to withdraw your baby from this research project, please notify a member of the research team before doing so. If you do withdraw consent during the research project, the study doctor and relevant study staff will not collect additional personal information from your baby, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor (the Murdoch Children's Research Institute) up to the time you withdraw your baby will form part of the research project results. If you do not want them to do this, you must tell them before your baby joins the research project.

15 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include:

- Generating enough information to answer the research questions.
- The end of funding and instruction from Government or the Murdoch Children's Research Institute (Research Sponsor).

16 What happens when the research project ends?

At the moment, we only have funds to collect data from your baby's hospital admission until they're discharged home and then when your child is 2 years of age. We may contact you in the future about enrolling your baby in follow-up projects, to investigate the longer-term effects of your baby's lung growth and function into childhood. Any such project will have ethical approval. At the end of the research project, we may present the results at conferences and publish in medical journals. We will do this in a way that does not identify your baby.

Part 2 How is the research project being conducted?

17 What will happen to information about the participant?

By signing the consent form you agree and consent to the study doctor and relevant research staff collecting and using personal information about your baby for the research project. Any information obtained for the purpose of this research project that can identify your or your baby will be treated as confidential and securely stored.

We may store your baby's identifiable information at the hospital(s) your baby is being cared in. Your baby will be allocated a unique study code. There will be one Master List which will contain the name of your baby and the assigned study code. No one outside of the immediate study team will know the true identity of you and your baby. Only the unique study code is used on any study data forms. The data and information that are sent to the sponsor of the study and any other involved parties only contain the study code assigned, but not your name, initials, or other personal data with which you can be identified. The data cannot be traced back to you in reports and publications about the research.

We will store your baby's electronic information securely on an internal server. We will keep paper copies of your baby's information in a locked filing cabinet in the MCRI and/or your baby's NICUs research centre.

Accessing your data for verification

Your baby's health records, and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the Sponsor, MCRI, the institution relevant to this Participant Information Sheet, *[Name of institution]*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

Your baby's information will only be used for the purpose of this research project and disclosed with your permission, except as required by law.

Information about your baby may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form, you agree to the research team accessing health records if they are relevant to your baby's participation in this research project.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about your baby. You also have the right to correct any information that you disagree with. Please contact the research team member named at the end of this document if you would like to access your baby's information.

The ultrasound and EIT images will be stored on the secure server at MCRI. We will store the ultrasounds and EIT images under the same unique study code as the rest of your baby's information. There will be no

identifiable details associated with the ultrasound videos or EIT data. The images taken may be used as part of education programs or research presentations, as well as in the final publication of this project and future research projects.

Some individuals may also access all of your data including access to the non-coded data. This is necessary in order to monitor whether the research has been carried out properly and reliably.

As part of the study, the Principal Investigator and the study team may disclose your baby's personal health information to those listed below:
Individuals or organisations responsible for administering the study:

- The lead investigator Prof David Tingay and members of the research team
- Murdoch Children's Research Institute Data Coordinating Centre
- The *[Name of Institution]* may disclose your baby's personal health care information from this research project to your baby's referring hospital in order to better manage your baby's care; and the follow-up clinics may disclose information to your baby's primary care physician.

Retention Period of data
Information will be kept for 25 years. The hard copy will be shredded and disposed of at the end of this period. The electronic data will be deleted in a secure manner. Some of your baby's information may be held in a research database indefinitely. Information that would identify you or your baby will not be held. However, the *[Name of Institution]* may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorisation to do so
- The Royal Children's Hospital Human Research and Ethics Committee grant permission after ensuring that appropriate privacy safeguards are in place
- It is required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of public forums, such as medical conferences. In any publication and/or presentation, information will be provided in such a way that your baby cannot be identified, except with your permission.

Data Sharing

To advance science, medicine, and public health, we also share your anonymised data with other ethically approved research projects or medical journals. When we do this, we will remove any identifying details and give the data a special code number. Only the research team can associate your name with their unique study code. We will take security measures to protect your data, if and when we give it to other people. You are unlikely to be identified by anyone other than this research project. In the unlikely event that this happens, someone from the research team will contact you. If you think you may have been re-identified, please let us know.

Transfer of Data to Countries outside of Australia

The study team also uses a third-party software platform to manage study-related documents. In doing so, some limited personal information such as you and your babies' initials, date of birth and contact details may be securely stored off site within this platform.

The platform is hosted in Europe and has been carefully chosen by the Murdoch Children's Research Institute so that your personal information will be stored securely and processed only in accordance with applicable data protection and privacy laws and regulations including the Australian Privacy Act and the European General Data Protection Regulation (GDPR). The vendor of the platform is required to comply with strict confidentiality obligations and is not permitted to share your personal information with any third parties whatsoever.

Registration of the Study

A description of this study is available on https://www.anzctr.org.au (# Registration Number TO BE INSERTED). This website will not include information that can identify you or your baby. You can search this website at any time.

18 Complaints and compensation

If you or your baby suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and we will help you with arranging appropriate medical treatment. If your baby is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

You will not lose any legal rights by signing this form.

19 Who is organising and funding the research?

This research project is being conducted by the BLUEPRINT Research Group, led by Professor David Tingay at the Murdoch Children's Research Institute. The MCRI may benefit financially from this research project if, for example, the project helps MCRI obtain approval for a new treatment.

Neither you nor your baby will benefit financially from taking part this research project even if, for example, your baby's samples (or knowledge acquired from analysis of the samples) prove to be of financial and commercial value to the MCRI.

In addition, if knowledge acquired through this research leads to discoveries resulting in commercial value to the MCRI, the study doctors or their institutions, there will be no financial benefit to you, your baby or family from these discoveries.

No member of the research team will receive a personal financial benefit from your baby's involvement in this research project (other than their ordinary wages).

20 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *The Royal Children's Hospital (Melbourne)*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

21 Further information and who to contact

The contact person may depend on the nature of your query.
If you want any further information concerning this project or if your baby has any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the study doctor on *[phone number]* or any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to the research site your baby is taking part in, the details of the local site complaints person are:

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

You can contact the Director of Research Operations at The Royal Children's Hospital Melbourne if you:

a. Have any concerns or complaints about the project
b. Are worried about your rights as a research participant
c. Would like to speak to someone independent of the project.
d. The Director can be contacted by telephone on (03) 9345 5044.

Local HREC Office contact (Single Site - Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form – Parent/Guardian

Title	*Predicting Long-term Outcomes of Prematurity from Early Life Events*
Short Title	*The BLUEPRINT Study*
Protocol Number	*107608 V1.2*
Project Sponsor	*Murdoch Children's Research Institute*
Co-ordinating Principal Investigator	*Professor David Tingay*
Site Principal Investigator	*[Principal Investigator]*
Location	*[Location]*

Declaration by Parent/Guardian

I have read the Participant Information Sheet, or someone has read it to me, in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my baby participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

I understand that discussion of this study may be held in person, by telephone, through telehealth appointments, or similar remote digital videoconferencing platforms.

I give permission for my baby's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *Murdoch Children's Research Institute* concerning my baby's condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I give permission for *[Name of Institution]* or the Murdoch Children's Research Institute to contact me to organise follow up when my baby approaches 1 and 2 years of age

Optional Consent

☐ I do	☐ I do not	I give permission for the collection of information about my race/ethnicity
☐ I do	☐ I do not	I give permission for the collection of my current postcode
☐ I do	☐ I do not	I give my permission for any residual blood to be used in future testing of emerging blood proteins related to lung injury.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Name of Witness* to
Parent/Guardian's Signature
(please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

- I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian of the participating baby has understood that explanation.

Name of Study Doctor/
Senior Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation – Parent/Guardian

Title	*Predicting Long-term Outcomes of Prematurity from Early Life Events*
Short Title	*The BLUEPRINT Study*
Protocol Number	*107608 V1.2*
Project Sponsor	*Murdoch Children's Research Institute*
Co-ordinating Principal Investigator	*Professor David Tingay*
Principal Investigator	*[Principal Investigator]*
Location	*[Location]*

Declaration by Parent/Guardian

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their health care, routine treatment, relationship with those treating them or relationship with *[Institution]*.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

In the event that a baby's withdrawal is communicated verbally, the Study Doctor/Senior Researcher must provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawing from the research project and I believe that the parent/guardian of the baby has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.