PARTICIPANT INFORMATION SHEET:
CONSENT FOR COLLECTION OF OUTCOME DATA

TITLE: Effect of breathing support during delayed cord clamping (DCC) for very preterm infants.

Short title: The ABC study ‘Assisted Breathing before Cord Clamping’.

PRINCIPAL INVESTIGATOR
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Clinical Nurse Specialist – Advanced Neonatal Practice
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Your baby is eligible to take part in this study as they were born prematurely (before 31 weeks) and received delayed cord clamping at birth as part of usual care. There is no obligation for your baby to take part and your baby’s care will not be different if you choose not to take part.

Background Information
Preterm babies and especially those born less than 31 week gestation are vulnerable and often need a blood transfusion as part of their care. We know that blood transfusions have risks. To help prevent blood transfusions, the practice of allowing up to a minute before the umbilical cord is clamped (delayed cord clamping) has been widely studied and is recommended in many hospitals including our own. By allowing time before the cord is clamped, blood flows from the placenta to increase baby’s blood volume. Babies that breathe before the cord is clamped receive more blood from the placenta than those that don’t breathe. The usual standard practice is to wait up to a minute before clamping the cord. This is the case whether baby is breathing or not. Once the cord is clamped, if the baby is still not breathing or has a low heart rate, the attending staff would provide breathing support. In this study we carried out all the standard procedures but also provided breathing support if needed to one group of babies while the cord was still attached. Not only could this reduce the need for blood transfusions but may also help the blood flow in the lungs and brain to be more stable in the early period after birth. Randomised controlled trials like this study are very important to inform us if we should be changing our routine practice. The best way to make a decision if breathing support should be part of standard care in the future; is to perform the study and to gather knowledge in a scientific way.

Aim
The aim of this study is to determine if adding breathing support before the cord is clamped will prevent some blood transfusions and improve hospital outcomes for premature babies.

What happens during the study?
Most preterm babies born in this hospital receive delayed cord clamping as part of standard best practice. Our current usual practice for babies who are not breathing during delayed cord clamping is to watch the baby carefully but allow the delayed cord clamping to take place.
If your baby was born unexpectedly, we will have assessed your baby’s breathing at birth and already have assigned your baby to receive standard treatment or breathing support while delayed
cord clamping was taking place. If your baby was breathing before the cord was clamped, the cord will have been clamped at 50 sec (standard care). If your baby was not breathing regularly but appeared in good condition your baby may have had:

1: Breathing support from 20 -50sec while delayed cord clamping was taking place,

or

2: Breathing support after 50sec of delayed cord clamping.

If your baby was assigned to receive breathing support while delayed cord clamping was taking place, your baby received breathing support a bit earlier than usual. Our standard practice is to wait until the cord is clamped. Giving breathing support earlier has been approved by the Northern Ethics Committee. We are now asking if you would allow us to collect information about your baby’s birth and information from baby’s hospital records so that we can answer this very important question. Your baby’s care in hospital will be the same whether they received breathing support or not and baby and parents will not be identifiable in any reports about the data collected.

Which treatment will your baby get and for how long?
Whether your baby was in the group that received breathing support before the cord was clamped will be decided at random. This is like tossing a coin to decide which group they are in. Neither parents nor staff will be able to decide which group your baby went into. If baby’s condition was thought not to be satisfactory before the cord was clamped, the delayed cord clamping would have been stopped early (also in keeping with our usual practice). At times the umbilical cord may be too short to allow us to give breathing support and if this was the case your baby would have received standard practice without breathing support.

Is there a benefit?
We suspect that babies who receive breathing support before the cord is clamped may not need as many blood transfusions and may have fewer complications during the hospital stay. In particular, there is potential to reduce the risk of brain bleeding and severe lung disease.

Is it safe?
We do not anticipate any risk to your baby from entering this study. We anticipate that providing breathing support a bit earlier than usual will not cause any additional risk to your baby. We will work with the midwife and/ or the obstetrician to keep the field sterile if there is a caesarean birth and to keep baby warm during the procedure (a sterile plastic warp is used as part of routine care).

Compensation
In the unlikely event of a physical injury to your baby as a result of participation in this study, you may be covered by ACC. ACC cover is not automatic, and your case would need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted
by ACC, you still may not get any compensation. This depends on factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses. There may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

**Blood Tests**
No additional blood tests will be taken from your baby should you decide to join this study.

**Taking part in the study**
To take part in this study the research team will discuss the study with you within 24 hours of baby’s birth. We will only collect information about your baby’s condition at birth and admission to the neonatal care unit if you agree to take part in the study. If you agree to take part we will also collect information from the first heart scan, tests results and hospital records as well as baby’s follow up examination at 2 years of age. If you choose not to take part in the study, we will not be collecting any information about your baby.

**Confidentially**
No material which could personally identify you or your baby will be used when we report results of this study. Paper records will be kept in a locked filing cabinet in the clinical nurse specialist office and computer data is password protected and will only be available to the investigators. Records are kept for 26 years then destroyed (shredded) or deleted from the computer. Hospital records for your baby will also be used to provide information for the study.

**Other Information**
- You can get more information about the study from investigators - Elizabeth Nevill, Dr Mike Meyer, Dr Lindsay Mildenhall, Jonathan Barrett, Dr Athol Johnson, or the research nurse. Research team contact: 09-2760044 ext 7263/8364
- If you need an interpreter, one can be provided.
- You are also welcome to request a cultural whaanau support person to help you understand more about the study.
  - Māori Health contact: 09-2760138/ 021817854
  - Pacific Health Unit support: 09-2760044 ext 9006/ 2952 or 0274805112
- Parents/guardians may request results of the study on the consent form. There is often a delay of around 1-2 years from the start of the study.
- If you have any questions or concerns about your rights as a participant in this study you may wish to contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Telephone (NZ Wide) 0800 555 050 Free Fax (NZ Wide) 0800 2787678 (0800 2 SUPPORT) Email (NZ Wide) advocacy@hdc.org.nz
You can also contact the health and disability ethics committee (HDEC) that approved this study on details below. Quote this reference number (15/NTA/146)
Phone: 0800 4 ETHICS
Email: hdecs@moh.gvt.nz

Please feel free to contact the researchers if you have any questions about this study.
CONSENT FORM

PROJECT TITLE: The ABC study (short title)

Request for Interpreter

<table>
<thead>
<tr>
<th>Language</th>
<th>Translation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>I wish to have an interpreter</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Māori</td>
<td>E Hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero</td>
<td>Ae</td>
<td>Kao</td>
</tr>
<tr>
<td>Samoan</td>
<td>Oute mana’o ia iai se fa’amatala upu.</td>
<td>Io</td>
<td>Leai</td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fiema’u ha fakatonulea</td>
<td>Io</td>
<td>Ikai</td>
</tr>
<tr>
<td>Cook Island</td>
<td>Ka inangoro au I tetai tangata uri reo</td>
<td>Ae</td>
<td>Kare</td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke fakaanga e taha tagata fakahokohoko kupu</td>
<td>E</td>
<td>Nakai</td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Io</td>
<td>Sega</td>
</tr>
<tr>
<td>Tokelaun</td>
<td>Ko au e fofou ki he tino fakaliliu te gagana Peletania kin a gagana o na motu o te Pakefika</td>
<td>Io</td>
<td>Leai</td>
</tr>
</tbody>
</table>

I/we have been invited to participate with my/our baby in ‘The ABC study’.

I/we have read and understood the Participation Information Sheet dated January 2016 for volunteers taking part in the study. I/we have had the opportunity to discuss the study. I/we am/are satisfied with the answers I/we have been given.

I/we have had the opportunity to use whaanau/cultural support to help me/us ask questions and understand the study.

I/ we understand that:
- Taking part in this study is voluntary (my/our choice)
- My/our baby and I/we can withdraw from the study at any time this will in no way affect my/our baby’s or my/our future health care in any way
- My/our participation in this study is confidential and that no material that could identify me/us or my/our baby will be used in any study reports
- Only one parents consent is required for my/our baby to take part in the study
I/we have had time to consider whether to take part

I/we know who to contact if I/we have any questions about the study and understand that at the end of the study I/we will be able to request information regarding which group my/our baby was in.

I/we agree to the research team having access to medical information and hospital records concerning the health of my/our child. YES/NO

I/we wish to receive a summary of the results of this study. YES/NO

I/we would like my/our baby’s GP to be informed of baby’s participation in this study. YES/NO

PROJECT TITLE: The ABC study

I/we consent to the participation of my/our baby, ___________________ in the study described above.

Parent’s Full Name: _____________________________

Signature of Parent: _____________________________ Date: _____________________________

Parent’s Full Name: _____________________________

Signature of Parent: _____________________________ Date: _____________________________

Investigators: Neonatal Unit, Middlemore Hospital, Auckland

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Project explained by:

Name: _____________________________  Role: _____________________________

Signature of Researcher: _________________  Date: _____________________________