**Participant Information Sheet**

**Study Title:** The BEAD Feasibility Study: A Baby Head ElevAtion Device for fully dilated caesarean sections

 You are being asked to take part in the BEAD Feasibility Study

**Co-Investigators:** Dr Jordon Wimsett, Dr. Lynn Sadler, Dr. Charlotte Oyston, Dr. Meghan Hill, Dr. Robin Cronin, Dr. Karaponi Okesene-Gafa, Dr. Matthew Drake, Dr. Erena Browne, Dr. Jane Alsweiler, Dr. John Thompson

*We acknowledge māmā and pēpi as taonga and the significant place they hold within whānau, hapū and iwi as the keepers and preservers of whakapapa. Through this study we hope to determine whether the Fetal Pillow® will improve health outcomes for māmā and pēpi in Aotearoa and globally.*

**WHAT IS THE PURPOSE OF THE STUDY?**

The BEAD Study is looking for people who need a caesarean section in labour at full dilatation (i.e. cervix is 10 cm dilated). We are studying whether a widely used medical device makes birth safer for mothers and babies.

In New Zealand around 1,500 patients undergo a caesarean section at full dilatation each year. Caesarean section at this stage of labour can be associated with increased risks for mother and baby, often due to the baby’s head being low in the pelvis at the time of surgery. These risks can be immediate (injury to womb or cervix or baby) or long-term (increased risk of preterm birth in a future pregnancy).

There is a medical device called the Fetal Pillow® which is inserted into your vagina before caesarean. The Fetal Pillow® is a small, soft silicone balloon that has been developed to try and elevate (lift) baby’s head to make delivery easier and reduce the risk of injuries to mother and baby. Although many maternity hospitals in New Zealand often use this device, there is not enough research to determine whether it reduces the risks associated with full dilatation caesarean. Using the device does not cause any harm to mother or baby, but the device is costly and it takes a couple of minutes to place, so if it is not effective, obstetricians should stop using it.

We are planning a trial to decide whether the device does make birth safe, and whether we should continue to use it.

**The purpose of this study** is to find out if a large trial of the Fetal Pillow® use is possible. To do this we need to understand whether people will agree to take part, and the things that either prevent or help them complete the study. The information collected in this study will also be included in any larger study of the Fetal Pillow® which occurs as a direct of this study.

**WHO CAN TAKE PART IN THE STUDY?**

The study will be undertaken at two hospitals: Te Toka Tumai Auckland and Te Whatu Ora Counties Manukau in Auckland, New Zealand.

You can take part in this study if you are pregnant with one baby that is head down (cephalic) and if you are more than 37 weeks pregnant when you are in labour, and need a caesarean section when you are 10cm dilated.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

If you agree to take you will have the balloon (Fetal Pillow®) placed in your vagina under the baby’s head immediately before your doctor starts the caesarean. Your anaesthetist will enter your hospital number into a computer research database which will randomly allocate you to one of two treatment groups. This will be done by chance - like tossing a coin - so you have an equal chance of being in either group.

* Group A: The balloon will be inflated (with 180mLs of water), and then deflated and removed after the baby is born.
* Group B: The balloon will not be inflated, and will be removed after the baby is born.

As a participant of the study, you won’t be able to choose your treatment group and neither you nor your surgical team will know whether the balloon has been inflated.

A member of our research/study team will visit you following your birth and ask your consent to collect information about you and about your baby. This information will be collected from your hospital record and include information about your health up to 6 weeks after your birth.

We know that complications of caesarean are linked with preterm birth. As a sub-study, we are interested in seeing if you have a preterm birth in a future pregnancy, and will also ask if you consent to our research team finding if you have another birth in the next 5 years and whether this next birth is preterm (<37 weeks) and whether your labour starts naturally in this birth. This information will be requested from the Ministry of Health so that we can know about births at hospitals in NZ other than the one where you had your Caesarean section. You will not need to have any tests for the study after the birth.

We would also like to ask you some questions about your knowledge of the study before your labour, and how you feel about taking part in the study.

**WHAT ARE THE BENEFITS OF THE STUDY?**

* We cannot promise that you or your baby will benefit from this study. We do not think taking part in the study will harm you or your baby. If the device reduces injury to your womb (uterus) then you may benefit from being in the group where the balloon is inflated.
* The results of this study will be used to inform a larger study on the use of the Fetal Pillow®.
* The results of this study will be used to improve the care of patients requiring an emergency caesarean section at full dilatation in the future.

**WHAT ARE THE RISKS OF THE TREATMENTS?**

There have been over 1,300 births reported in the literature with no reports of complications from use of the Fetal Pillow®.

**WHAT WILL HAPPEN TO MY INFORMATION?**

During this study the doctors, clinical staff and researchers will record information about you and your study participation. This includes information from your hospital records. In order to take part in this study we need your consent to collect this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

* Research staff (to complete study assessments)
* Your lead maternity carer (LMC) will be notified of your participation in this study with your consent.
* The University of Auckland (sponsor) study monitors, to make sure the study is being run properly and that the data collected is accurate.
* The sponsor and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
* The sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study team. Instead, you will be identified by a code. The study team will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

Coded data may be shared locally or overseas to include with data from other similar studies.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information

If you agree, we will ask the Ministry of Health to match your identifiable data to births in NZ up to 5 years after your Caesarean. We will ask when you delivered your next baby, what gestation your baby was at birth, and whether your labour started spontaneously prior to that birth. This information will be managed securely the same as the information collected at the time of your Caesarean. In other words, it will be housed at the University of Auckland, it will be de-identified, and it will be retained for 26 years after you agreed to participate in the study.

Your coded information may be used for future research related to Caesarean section and the risk of preterm birth.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information

Your identifiable information is held at the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for at least 26 years, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information. In this study, the information collected is routine information and should not place you at any risk.

Your anonymised information may be sent overseas. If this is the case, a researcher involved in this study will be included in the group which makes decisions about the use of your information nto ensure that analysis and interpretation is culturally appropriate for New Zealanders.

Data-Linking

In this study we would like to link your study information with the maternity dataset in New Zealand to determine whether you have another baby within 5 years of your Caesarean and whether this baby is born preterm. This is called ‘data-linking’. Data-linking in this study is optional.

In this study we will link your national health identifier (NHI number) to your next birth in NZ.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

* We have consulted with staff at Iwi United Engaged (an organisation working alongside researchers to ensure research is culturally safe for Māori), Māori midwives and a Māori researcher/co-investigator (Erena Browne) about the collection, ownership, and use of study data as well as the study design.
* Any analyses describing outcomes among participants of Māori ethnicity will be planned, interpreted, and disseminated in consultation with our Māori co-investigator and further korero around the results and their significance for Māori is planned.
* We will allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

**WHO PAYS FOR THE STUDY?**

This research is being conducted by a collaborative group of clinical researchers in New Zealand. Funding is currently provided by the Health Research Council of New Zealand and the Mercia Barnes Trust. The medical devices (Fetal Pillows®) used in the study have been purchased from the medical device company (Cooper Surgical) and the company have no role in the design or running of the study. There are no additional costs to you for taking part in the study.

**WHAT ARE MY RIGHTS?**

Participation in The BEAD Feasibility Study is completely voluntary. You are free to decline to participate or withdraw from the study at any time. You do not need to provide a reason to withdraw but we will provide you with an opportunity to give us feedback if you wish. If you choose not to participate, or you withdraw from the study, this will not affect the care you receive during or after the birth of your baby. With your consent, data collected prior to your withdrawal will be used in study analysis.

As a participant in the study you have the right to access all information collected about you and your baby for the purposes of the study.

Participants can ask to receive the results of this study. This might include receiving a summary of the findings of the study, and copies of any publications arising from this study.

**WHAT IF SOMETHING GOES WRONG?**

We do not anticipate that taking part in the study will increase your risk of injury. If you or your baby were injured in this study, you would be eligible to apply for compensation from ACC just as you would

if you were injured in an accident at work or at home. This does not mean that your claim will be automatically accepted. You will have to lodge a claim with ACC, which may take some time to assess. If you claim is accepted, you will receive funding to assist with your recovery.

**WHO DO I CONTACT FOR FURTHER INFORMATION OR IF I HAVE CONCERNS?**

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| Dr. Jordon WimsettPrincipal InvestigatorPhone: 021355828Email: thebeadstudy@auckland.ac.nz | Dr. Lynn SadlerCo-ordinating investigator, Te Toka Tumai AucklandEmail: LynnS@adhb.govt.nz |

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| If you want to talk to someone who isn’t involved in the study, you can contact an independent health and disability advocate on:Phone: 0800 555 050Fax: 0800 2 SUPPORT (0800 2787 7678)Email: advocacy@advocacy.org.nzWebsite: https://www.advocacy.org.nz/ | If you require Māori cultural support, you may contact the administrator for He Kamaka Waiora (Maori Health Team) on: Phone: 09 486 8324 ext 2324 | You can also contact the health and disability ethics committee (HDEC) that approved this study on: Phone: 0800 400 569 (Ministry of Health general enquiries)Email: hdecs@health.govt.nz |