**Participant Information Sheet / Consent Form**

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| **Interventional Study – Woman providing own consent** |

**Participant Copy – To be retained by the participant**

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| --- | --- |
| **Title** | Use of the REBozoTEChnique in second stage labour to reduce the incidence of assisted vaginal births for nulliparous women with epidurals: A mixed methods feasibility study |
| **Short Title** | REBTEC Pilot Trial |
| **Protocol Number****Project Sponsor****Principal Investigator** | Version 2The University of QueenslandMrs Kathy Ball |
| **Advisors**  | Dr Nigel Lee; Associate Professor Victoria Eley; Professor Tracy Humphrey |
| **Location** | [INSERT SITE NAME] |

# Introduction

You are invited to participate in a research project entitled the REBTEC pilot trial. The REBTEC pilot trial will examine a traditional midwifery technique used by some midwives, called rebozo, to prevent or correct the effect that labour and epidurals may have on the position of the baby within the mother’s pelvis. Most midwives in Australia are either aware of the rebozo technique, or use it in their practice. All first-time mothers giving birth at this hospital, who have had a low-risk pregnancy, and who do not have any complications (eg. small/growth restricted babies, insulin-controlled diabetes, pelvic instability, serious medical conditions), and who are using, or who intend to use, epidural analgesia, are being invited to participate in this REBTEC pilot trial.

This Participant Information Sheet/Consent Form explains the purpose of this research project. It is important for you to understand why this research is being done, and what it will involve, to help you decide if you want to take part in this research.

Please read this information carefully and take your time to make your decision and ask any questions about anything that you do not understand or want to know more about. Before deciding whether, or not, to take part, you might want to talk about it with your support person, relative, friend or your local doctor. If you agree to participate you will be asked to sign the Participant Consent Form, once your epidural is sited and you are pain and anxiety free.

If you decide you want 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 take part in the research project.
* Consent to be placed in one of two groups in second stage labour, either the rebozo group or standard care group.
* Consent to the use of de-identified information collected to be used for this research project.

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

# What is the purpose of this research project?

This research project forms part of the PhD studies of Mrs Kathy Ball. The project is funded and co-ordinated by The University of Queensland.

The purpose of this research project is to improve our understanding of the use of the rebozo technique during labour and birth. Specifically, this study will examine the use of the technique during labour and the processes needed to conduct a larger trial. Malposition can be defined as baby’s back against mother’s back. When this happens, it is difficult for the baby to navigate its way through the mother’s pelvis. This means your baby may need help to be birthed, using a vacuum or forceps. Epidural use can also impact the baby’s ability to rotate to the appropriate position for birth, increasing the likelihood of malposition and assistance with birth. The rebozo technique involves your midwife gently rocking you from side to side, which should take approximately five minutes in total, to encourage the baby into the best position for birth.

# What will happen if I agree to be a part of this research project?

Participation in this research is voluntary and your written consent will be obtained once your epidural has been inserted and is working well. If you decide to participate, you will be randomly placed in either the group who receives i) rebozo technique; OR ii) usual care (excluding rebozo). You will have an equal chance of being in either group. This is done so we are able to determine which method works better. Your primary midwife will not be able to control which group you are assigned, you will be allocated by chance.

The rebozo technique involves using a folded sheet, placed under your hips. Two midwives , one on each side of you, will rock you four times, then you will rest for two minutes on your left side, and then this process is repeated immediately (please see image below as an example). Once the rebozo technique has been completed, the rebozo will not be used again. The standard care group will involve your primary midwife suggesting methods to correct malposition that they would routinely use. Some examples of this are placing a pillow or ball between your legs, moving you periodically from one side or the other, increasing the strength of your contractions with a synthetic drug called oxytocin. The standard care group will not be able to use the rebozo technique. A short survey of approximately 5 minutes, within two weeks of giving birth, will complete your involvement in the research project, pending your consent. You will be contacted via your preferred contact, either email or text, with a link to the survey. There will be two reminder emails/texts thereafter.

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*Image from Cohen and Thomas, 2015.*

**4. Other relevant information**

We will recruit 120 women who are giving birth for the first time, where 60 women per group will be allocated to either group in the study. This research project is a collaboration between The University of Queensland and [INSERT SITE NAME].

**5. Do I have to take part in this research project?**

Taking part is entirely voluntary. You may choose to take part, not to take part, or you may change your mind at any time without having to give a reason. If you decide not to participate or change your mind at any time, it will not affect your care.

There are no payments or compensation associated with participation in either the pilot randomized controlled trial or the short survey to follow.

# What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. Primarily, this research aims to further knowledge that may improve the care that is received by other women in the future.

1. **What are the possible risks of taking part?**

It is possible that the rocking motion may cause dislodgement of the epidural or the cannula. This risk exists for all women in labour so epidurals and cannula are attached securely using dressings and tape. We will check that the epidural and cannula are securely attached before and after the rebozo technique is used. While the rebozo technique has not been formally studied for efficacy and safety, there have not been any reports from use in practice of any risks or side effects. The lead researcher will constantly assess and monitor the trial as it progresses, for any safety issues.

It is possible that you may experience distress or anxiety when completing the survey about your birth experience. If this happens we would ask you to stop taking the survey, and access, if necessary, your General Practitioner, Beyond Blue or Lifeline, for additional counselling support services.

# What will happen to information about me?

By signing the consent form, you consent to the principal investigator and her supervisors, and relevant research staff, collecting and using personal information about you, which will remain confidential, for this specific research project. This data, collected via [INSERT SITE NAME] Data Custodian, will remain securely stored, locked, password protected and only accessible by The University of Queensland (UQ) research team. The UQ research team would like to collect information about your labour and birth and your baby’s health, but only as it relates to this research. We would like to collect data on your ethnicity, marital status and socio-economic status. Additionally, information about this pregnancy, your labour and birth, and information about your baby, such as weight and condition at birth. With your consent [INSERT SITE NAME] Custodian will provide us with the necessary details from your health records. Personal information such as your name, telephone and email address will only be used to contact you after you have gone home from hospital, if you agree to participate in the brief follow-up survey. Your unique hospital record number may be used to obtain your hospital data, and this will be removed after your hospital data is linked with the data collected during your labour. Paper copies of your information will be stored in locked cupboards and electronic records within password protected files at The University of Queensland. Only authorised members of the UQ research team will have access to your information. Responsible members of the [INSERT SITE NAME] and The University of Queensland may be given access to data for monitoring and/or audit of the study to ensure that we are complying with regulations. The information that you provide to us will be combined with anonymised information from other participants before it is analysed by the researchers. Use of your data means we will never use your name, or that of family members, or any other personal details such as your address.

1. **What happens when the research ends?**

When the research project ends the data will be analysed and the results published in peer reviewed journals and presented at conferences. The findings will also be available to hospitals and health authorities. As the aim of this study is to assess the processes for a larger trial the rebozo technique will not be available immediately. A summary of the results of this research will be available to participants on request once analysis and peer review is completed. Participants can contact the lead researcher, Kathy Ball, via email kathy.ball@uqconnect.edu.au, for this information.

## What if I withdraw from this research project?

You can change your mind about being in this research at any time and you don’t have to say why. If you decide to withdraw from the project, please notify a member of the research team.

If you do withdraw your consent during the research project, the research staff will not collect additional information from you. Although we may ask your consent to include any data collected up until the stage at which you withdrew.

# Complaints and compensation

The person you may need to contact will depend on the nature of your query. If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical or counselling treatment. If you are eligible for Medicare, you can receive any medical or counselling treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact Mrs Kathy Ball: Ph 0437004331; e: kathy.ball@uqconnect.edu.au).

If you do not feel comfortable contacting the research staff personally, you may contact the Metro South Health Service Ethics Committee (3443 8049). Please mention that your call is about the REBTEC pilot trial, and quote trial number 88039. Any complaints you make will be treated in confidence and investigated fully and you will be informed of the outcome.

1. **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 Metro South Health and The University of Queensland.

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.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the following people:

**Research Project contacts:**

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| Principal Investigator (24hrs) | Mrs Kathy Ball | Ph: 0437004331 | kathy.ball@uqconnect.edu.au  |
| Principal Advisor | Dr Nigel Lee | Ph: 0427231390 | nigel.lee@uq.edu.au |
| [INSERT SITE CONTACT PERSON DETAILS] |  |  |  |

If you have any complaints about any aspect of the research project, the way it is being conducted or any questions about being a participant in general, please quote the trial number 88039 and contact the ethics HREC Co-ordinator on:

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| Telephone | 34438049 |
| Email | MSH-Ethics@health.qld.gov.au |

**[INSERT SITE NAME] Governance and Ethics oversight contact:**

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| --- | --- | --- |
| [INSERT SITE GOVERNANCE CONTACT DETAILS] |  |  |

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**Research Project: Consent to Participate**

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| --- | --- |
| **Title** | Use of the REBozoTEChnique in second stage labour to reduce the incidence of assisted vaginal births for nulliparous women with epidurals: A mixed methods feasibility study |
| **Short Title** | REBTEC Pilot Trial |
| **Protocol Number****Project Sponsor****Principal Investigator** | Version 2The University of QueenslandMrs Kathy Ball |
| **Advisors**  | Dr Nigel Lee; Professor Victoria Eley; Professor Tracy Humphrey |
| **Location** | [INSERT SITE NAME] |

**Declaration by Participant**

By signing this form, I confirm that:

* The research project has been fully explained to me in a language that I understand.
* I have had an opportunity to ask questions and am satisfied with the answers I have received.
* I authorise access to my personal health and clinical information as explained in this form.
* I understand that the research information may be published (in print and/or electronically) and/or presented in a variety of forums without time limit.
* The research information will be provided in such a way that I cannot be identified.
* I freely agree to participate in this research project as described, and understand that I am free to withdraw my consent at any time before publication.
* I understand that once the research is written and published, it will not be possible to have the information recalled or deleted.

🞏 Yes 🞏 No

* I give permission for collected data from this research to be used in future research once ethical clearance for that project is obtained (if we do a bigger trial afterwards).

 🞏 Yes 🞏 No

* I agree to be contacted by email or text for a brief survey, via a link, of my experience in the REBTEC pilot trial.

 🞏 Yes 🞏 No

If Yes, Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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**Declaration by Midwife or Midwifery Researcher**

I have given a verbal explanation of the research project, processes and risks, and I believe that the participant has understood that explanation.

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|  | Name of Midwife or Midwifery Researcher (please print) |  |  |
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|  | Signature |  | Date |  |  |
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Note: All parties signing the consent section must date their own signature.

 **[INSERT SITE LOGO]**

**Withdrawal of Participation**

|  |  |
| --- | --- |
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| **Advisors**  | Dr Nigel Lee; Professor Victoria Eley; Professor Tracy Humphrey |
| **Location** | [INSERT SITE NAME] |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my future treatment, my relationship with those treating me or my relationship with [INSERT SITE NAME].

I give permission for data collected up until the point of withdrawal to be used in this research.

 🞏 Yes 🞏 No

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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**Declaration by Midwife or Midwifery Researcher**

I understand that the participant has withdrawn from this research project.

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|  | Name of Midwifery or Midwifery Researcher (please print) |  |  |
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|  | Signature |  | Date |  |  |
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Note: All parties signing the consent section must date their own signature.

In the event that the participant’s decision to withdraw is communicated verbally, the Midwife or Midwifery Researcher will need to provide a description of the circumstances below:

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Affix Hospital ID label here

**Research Project: Consent to Participate \*\*copy for woman’s file\*\***

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* The research information will be provided in such a way that I cannot be identified.
* I freely agree to participate in this research project as described, and understand that I am free to withdraw my consent at any time before publication.
* I understand that once the research is written and published, it will not be possible to have the information recalled or deleted.

🞏 Yes 🞏 No

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 🞏 Yes 🞏 No

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 🞏 Yes 🞏 No

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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**Declaration by Midwife or Midwifery Researcher \*\* copy for woman’s file \*\***

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| **Location** | [INSERT SITE NAME] |

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I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my future treatment, my relationship with those treating me or my relationship with [INSERT SITE NAME].

I give permission for data collected up until the point of withdrawal to be used in this research.

 🞏 Yes 🞏 No

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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**Declaration by Midwife or Midwifery Researcher**

I understand that the participant has withdrawn from this research project.

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|  | Name of Midwifery or Midwifery Researcher (please print) |  |  |
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  [INSERT SITE LOGO]

Affix Hospital ID label here

**Research Project: Consent to Participate \*\*researcher’s copy\*\***

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* I understand that the research information may be published (in print and/or electronically) and/or presented in a variety of forums without time limit.
* The research information will be provided in such a way that I cannot be identified.
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 🞏 Yes 🞏 No

* I agree to be contacted by email or text for a brief survey, via a link, of my experience in the REBTEC pilot trial.

 🞏 Yes 🞏 No

If Yes, Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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Note: All parties signing the consent section must date their own signature.

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**Declaration by Midwife or Midwifery Researcher \*\*researcher’s copy\*\***

I have given a verbal explanation of the research project, processes and risks, and I believe that the participant has understood that explanation.

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|  | Name of Midwife or Midwifery Researcher (please print) |  |  |
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|  | Signature |  | Date |  |  |
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Note: All parties signing the consent section must date their own signature.

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**Withdrawal of Participation \*\*researcher’s copy\*\***

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| **Location** | [INSERT SITE NAME] |

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I give permission for data collected up until the point of withdrawal to be used in this research.

 🞏 Yes 🞏 No

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  | Date |  |  |
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