**Participant Information Sheet / Consent Form**

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| **Non-Interventional Study –** Adult providing own consent |

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

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| **Title** | Use of the rebozo to correct malposition |
| **Short Title** | REBTEC Pilot Trial |
| **Protocol Number**  **Project Sponsor**  **Principal Investigator** | Version 1  The University of Queensland  Mrs Kathy Ball |
| **Advisors** | Dr Nigel Lee; Associate Professor Victoria Eley; Professor Tracy Humphrey |
| **Location** | Metro South’s Logan Hospital |

# Introduction

You are invited to participate in a research study of your experiences in the REBTEC Pilot Trial, and the interventions you usually use to help correct malposition. All midwives who participated in the pilot trial are being invited to participate in this study.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the process involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

You can decide whether you wish to take part in the research at any time.

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 having interviews recorded, whereby pseudonyms will be used to protect your identity.
* Consent to having de-identified data collected from the interviews to be published and/or presented at conferences.

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

**2 What is the purpose of this research?**

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 explore the experiences of midwives in the REBTEC Pilot Trial, using an intervention, either from the standard care group or rebozo group, to help with malposition.

**3 What does participation in this research involve?**

If you are considering participating in the study you can reply to the email or contact the research midwife directly by phone or text on 0437004331. The researcher will then contact you to answer any questions you may have and arrange to provide written consent. You will not incur any costs as a result of participation in the study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

**4 What do I have to do?**

In this research we ask you to participate in an interview with one of our researchers. The interview will take approximately one hour and be conducted using a recording device.

The researcher would like to ask questions about your practice experience and what participation in the trial was like for you, your thoughts, your feelings, as well as situations, events and people connected with your experience. There are no right or wrong answers, you do not have to answer any questions that you do not want to. You can ask to stop the interview at any time.

**5 Other relevant information about the research project**

The study is a follow on study to the REBTEC pilot randomised controlled trial that you participated in as a clinician. This phase will involve about 15 participants, who will all be interviewed separately.

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

Participation in the study is voluntary and you are not obliged to participate if you do not wish to. If you do, you can withdraw at any time. Before you make any decision regarding your participation you are encouraged to talk further with the researchers for additional information or clarification. You should only sign the consent form after you have been fully informed and you will be given a copy to keep.

You are free to withhold any information you prefer not to discuss and can decline to answer any questions we ask. Whatever your decision at any time, you can be assured that it will not affect your role at Logan Hospital/Metro South Health Service.

**7 What are the possible benefits of taking part?**

If you agree to take part you will not benefit directly from the study. However you will assist in expanding our knowledge and understanding of the interventions used in the REBTEC pilot trial.

**8 What are the possible risks and disadvantages of taking part?**

Whilst it is not anticipated that there will be any risks associated with participating in the study, talking about your clinical practice may at times be difficult for you. You are free to stop the interview at any time if you do not wish it to continue. If you feel you would like some additional help after the interview we will be able to advise you who to contact, for example Staff Advocate, Professional Representative or Counsellor.

**9 What if I withdraw from this research project?**

If you agree to take part, you are also free to change your mind at any time before or during the interview, and you do not have to give a reason. We will respect whatever decision you make. Once your interview is transcribed and your name removed from the transcript, it will not be possible to withdraw from the study.

**10 What happens when the research project 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. If you are interested in the final results of this project, you can request a summary of the report be sent to you.

**11 What will happen to information about me?**

All information (data) will be stored securely by The University of Queensland (UQ) in Brisbane. Paper transcripts of your interview will be stored in a locked cabinet within the researchers’ locked office. Electronic data (transcripts and audio recordings) will be stored on password protected computers. All data will be stored securely for a minimum period of five years. Only the UQ researchers will have access to the data. All data related to you will be given a unique study code (number) known only to the UQ research team. When your interview is transcribed, it will be de-identified meaning that we will never use your name, or that of any family members, or any other personal details such as your address.

**12 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 treatment. If you are eligible for Medicare, you can receive any medical 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 (Ph 3443 8049). Please mention that your call is about the REBTEC pilot trial. Any complaints you make will be treated in confidence and investigated fully and you will be informed of the outcome.

**13 Who is organising and funding the research?**

This research project is being conducted by PhD student Mrs Kathy Ball, and funded by The University of Queensland.

**14 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 contact person(s)**

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| --- | --- | --- | --- |
| Principal Investigator (24hrs) | Mrs Kathy Ball | Ph: 0437004331 | [kathy.ball@uqconnect.edu.au](mailto:kathy.ball@uqconnect.edu.au) |
| Principal Advisor | Dr Nigel Lee | Ph: 0427231390 | [nigel.lee@uq.edu.au](mailto:nigel.lee@uq.edu.au) |
| Birth Suite Manager & Associate Investigator | Mrs Karen Gould | Ph: 32998655 | [karen.gould@health.qld.gov.au](mailto:karen.gould@health.qld.gov.au) |

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| Reviewing HREC name | Dr Mary Boyde |
| HREC Executive Officer | Chair – Metro South Health Service HREC |
| Telephone | 34438049 |
| Email | [MSH-Ethics@health.qld.gov.au](mailto:MSH-Ethics@health.qld.gov.au) |

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, then you may contact:

**Reviewing HREC approving this Research Project and HREC Executive Officer**

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| --- | --- |
| Reviewing HREC name | Dr Mary Boyde |
| HREC Executive Officer | Chair – Metro South Health Service HREC |
| Telephone | 34438049 |
| Email | [MSH-Ethics@health.qld.gov.au](mailto:MSH-Ethics@health.qld.gov.au) |

**Metro South Governance and Ethics oversight contacts:**

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| --- | --- | --- | --- |
| Metro South Human Research Administrator | Maria Wojciechowski | Ph: 34438047 | [MSH-Research@health.qld.gov.au](mailto:MSH-Research@health.qld.gov.au) |

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**Research Project: Consent to Participate**

|  |  |
| --- | --- |
| **Title** | Use of the rebozo to correct malposition |
| **Short Title** | REBTEC Pilot Trial |
| **Protocol Number**  **Project Sponsor**  **Principal Investigator** | Version 1  The University of Queensland  Mrs Kathy Ball |
| **Advisors** | Dr Nigel Lee; Associate Professor Victoria Eley; Professor Tracy Humphrey |
| **Location** | Metro South’s Logan Hospital |

**Declaration by Participant**

By signing this form, I confirm that:

* 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 participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my relationship with Metro South Health Service.
* I understand that I will be given a signed copy of this document to keep.

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| --- | --- | --- | --- | --- | --- | --- |
|  | Name of Participant  (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by 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) | |  | | |  | |
|  | | | | | |  | |
|  | Signature |  | | Date |  | |  |
|  | | | | | | | |

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

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

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

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