Participant Information Sheet and Consent Form

Interventional Study - *Adult providing own consent*

Title	**A Feasibility, Randomised, Open-label, Parallel Group Study to Evaluate Safety and Efficacy of the Belly Bed in Reducing Sacroiliac Joint Pain, Lumbar Spine Pain, and Symphysis Pubic Pain Associated with Third Trimester Pregnancy**
Short Title	**The Belly Bed Trial**
Protocol Number	**TBB-CIP-01**
Project Sponsor	**The Belly Bed Pty Ltd**
Coordinating Principal Investigator/ Principal Investigator	*<< Insert >>*
Location	*<< Insert >>*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are in the third trimester of the pregnancy at between 27 weeks and 32 weeks gestation and have a documented history of pregnancy-related sacroiliac joint pain (hip), lumbar spine pain (lower back), and symphysis pubic pain for at least 4 weeks during this pregnancy. The research project is testing a new treatment for pregnancy related pain using the Belly Bed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

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 have the tests and treatments that are described
- Consent to the use of your personal and health information as described

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

2 What is the purpose of this research?

The Belly Bed is an experimental treatment. This means that it has not been approved by the Therapeutic Goods Administration (TGA) as a treatment for pregnancy-related pain in Australia, however the device has been on the commercial market as a concomitant device to help alleviate pregnancy related pain.

The purpose of this clinical study is to evaluate the safety and effectiveness of the Belly Bed in pregnant women in the third trimester at between 27 weeks and 32 weeks gestation and have a documented history of sacroiliac joint pain, and/or lumbar spine pain, and/or symphysis pubic pain during this pregnancy.

Your antenatal care provider has diagnosed you as having “pregnancy-related sacroiliac joint pain, and/or lumbar spine pain, and/or symphysis pubic pain during your pregnancy.” Pregnancy pain is a common problem among pregnant women and many researchers estimate that it impacts more than half of pregnancies which can be incapacitating if untreated or not treated appropriately. There are several factors associated with the development of pregnancy pain. As the fetus (baby) grows, the body’s centre of gravity shifts forward, and this increases the force applied to the sacroiliac joint straining surrounding muscles and joints, causing pain. Normal hormonal changes experienced with pregnancy increase the mobility of the ligaments surrounding the sacroiliac joints which can results in inflammation producing pain.

The Belly Bed is an advanced maternity airbed designed to provide relief for pregnancy related pain. The Belly Bed is divided into three different compartments of main bed, abdominal cavity and leg rest which can be independently inflated by an internal electronic air valve pump using the handheld remote control attached on the side. Once inflated, each compartment can be adjusted to accommodate the user’s need including the recessed abdominal cavity that can be adjusted to accommodate the different size of the growing abdomen throughout pregnancy.

Figure 1. The Belly Bed

This study is being sponsored by The Belly Bed Pty Ltd, the company that makes the Belly Bed being used in the study. As the sponsor of the study, The Belly Bed will be paying for the costs of the device and of the assessments being conducted in this study.

3 What does participation in this research involve?

If you agree to participate, you will be asked to sign this informed consent form and will be enrolled in the study. You will be asked to consent to screening tests to make sure that you qualify for this clinical study. If you pass the screening tests, you will be randomly assigned to one of two groups (Group A or Group B). This is called "randomisation." Participants in Group A will receive the Belly Bed to be used until delivery. Participants in Group B will not be given the Belly Bed and will continue to use their own bed at home.

As part of the study you will need to attend routine in-clinic visits outlined below. You will also have an ultrasound and fetal Doppler scan prior to starting the study (this is called the baseline visit) and at 36-weeks gestation. The purpose of the ultrasound and fetal Doppler scan is to monitor the growth of your baby. The study sponsor will pay for the cost of the ultrasound and Doppler scan.

Screening

A member of the study team will explain the study. If you are interested in participating, you will be asked to sign this informed consent form before being enrolled in this study. The study doctor and/or study coordinator will answer any questions you may have and will review the requirements of participation with you before any screening procedures are performed.

Tests to determine if you qualify to take part in a study are called "screening procedures." For this study, the screening procedures are described below.

- If you are at between 27 weeks and 32 weeks gestation, your medical history will be reviewed and you will be asked to complete an assessment known as Visual Analogue Scale (VAS) which is a simple way of classifying the severity of your pregnancy related pain to make sure you qualify for the study.

You will also have the following test carried out:

- Vital sign measurements: heart rate, blood pressure and respiratory rate (breathing rate).

Baseline

If you qualify to participate in this clinical study, you will have the following information collected and/or tests carried out before you are randomised into either Group A or Group B to check your overall health before study procedures begin and these will be used to compare the effectiveness of the Belly Bed throughout the trial:

- Demographics: age, ethnicity, height and weight
- Vital sign measurements: heart rate, blood pressure, and respiratory rate
- Visual Analogue Scale
- AQoL-8D: to measure the effects on quality of life of the participants
- Likert Scale: to assess the influence of pain on sleeping, getting up from sitting position, sitting down, walking, working and overall daily life.
- Oedema (swelling) measurement of lower limbs
- Assessment of mobility
- Ultrasound (Fetal and Doppler) to assess the growth of your baby
- Current pregnancy information

- Previous Medical History
- Record of concomitant medications and therapy

Randomisation

Once baseline procedures are complete, you will be randomly assigned (randomised) to one of two groups by chance, like the flip of a coin. Half (50%) of the participants will be assigned to "Group A" and will receive the Belly Bed to be used until delivery. The other half (50%) of the participants will be assigned to "Group B" and will not receive the Belly Bed and continue to use their own bed. Neither you, nor your study doctor, nor the sponsor of this study (Belly Bed Pty Ltd) will be able to choose your group assignment. This means that there is no guarantee that you will receive the Belly Bed upon randomisation. Signing this consent form means that you are willing to be part of the study, whether you receive the Belly Bed or not, and that you agree to remain in the study upon completion.

Group A - Study Procedures

If you are assigned to Group A, you will receive the Belly Bed to be used until delivery. You, and only you, will be required to use the Belly Bed instead of your own bed on daily basis. You will be provided with a Participant Sleep Diary which will be required to be completed daily until delivery. You are required to bring this diary to each scheduled site visit. The following information will be collected from the Participant Sleep Diary:

- Daytime sleepiness
- Sleeping position preferences and ability to sleep in these positions
- Total hours of continual sleep overnight
- Total time spent on bed during the day
- Type of bed slept
- Adverse event(s)
- New or change in your medication and/or therapy

You will receive sufficient training by study staff on how to complete the diary. If you have any questions throughout the course of your participation contact your study site staff.

Group B – Study Procedures

If you are assigned to Group B, you will continue to use your own bed and undergo the same study procedure as Group A, which includes completing the Participant Sleep Diary.

Follow Up Evaluations (Week 2, 4, 6 post-randomisation and 38 weeks gestation)

If you agree to participate in this clinical study, you must be willing to return for periodic follow-up evaluations until delivery, regardless of whether you are assigned to Group A or Group B.

You will be asked to return for study follow-up visits every 2 weeks after randomisation. At each follow-up visit you will have the following information collected and/or tests carried out to check your health status:

- Vital sign measurements: heart rate, blood pressure, and respiratory rate
- Visual Analogue Scale

- AQoL-8D: to measure the effects on quality of life of the participants
- Likert Scale: to assess the influence of pain on sleeping, getting up from sitting position, sitting down, walking, working and overall daily life.
- Oedema (swelling) measurement of lower limbs
- Assessment of mobility
- Adverse events
- New or change in your concomitant medication/therapy

You are also required to return the sleep diary completed for the past 2 weeks and be asked if there were any changes to concomitant treatments. You will be provided with a new diary at week 2, week 4, and week 6 for you to complete over the next 2 weeks.

If you report any health problems, the study coordinator or doctor may ask you to come in for further tests. The study doctor may also request that other tests be performed at any of the visits and if needed, may schedule you for additional visits. It is very important to attend all scheduled visits, whether or you are in Group A or Group B. Your information, regardless of outcome, is not complete without all visits.

If you move, or must miss a visit, the study team will make every effort to continue your evaluations.

36 Weeks

At 36 weeks, you would also be required to return for ultrasound (fetal and Doppler). The ultrasound is additional to routine care as the study doctor would like to assess the growth of your baby while you are participating in the study.

You would also be asked if you have experienced any adverse events.

Delivery

If you are still participating in the study, at the time of the delivery of the child, the following information regarding the delivery will be collected to evaluate the safety of the Belly Bed:

- Method of Delivery
- Duration of Labour
- Pain Medications
- Gestation
- Complications
- Birth Weight
- Bed Preference

If the delivery occurs unplanned or unexpectedly at another birth centre all information regarding the delivery will be obtained immediately after the delivery.

End of Study Visit

You will be asked to participate in an end of study telephone call at 30 days after the delivery. The intention of this visit is to collect post-delivery safety data for yourself and the baby. Upon the completion of end of study telephone call, you will be considered to have completed the study.

Cost for Participating in this study

You will not be paid for your participation in this study. You will not be asked to pay for any tests or visits required by this study and not required as part of your standard of care treatment these will be paid for by the study sponsor. For study-specific appointments you will be provided with a car park voucher to cover the cost of vehicle parking at Royal North Shore or North Shore Private Hospitals. If other transport costs are incurred, then please discuss this with the study coordinator to arrange reimbursement of costs. There will not be any additional costs to you to participate in this study.

You (or your private health insurer) will be billed for all medical expenses that arise during the course of this study that are not performed for study-related purposes only.

If you experience a complication or injury, please immediately contact your physician to insure proper attention and care. If you seek emergency care in any way, please tell the emergency doctor that you are a participant in a clinical research study. Your study card will provide the required study and contact information.

It is desirable that your local doctor be advised of your decision to participate in this research project. By agreeing to participate in this study you are agreeing to your antenatal care provider being told of your participation.

4 Other relevant information about the research project

Up to ninety (90) participants will be treated in this study at multiple study sites.

This is the first clinical trial performed to evaluate the Belly Bed.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

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

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[insert institution].*

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other treatment options for pregnancy related pain are: change in medication and postural techniques. The study doctor or study coordinator will discuss these options with you before you decide whether or not to take part in this research project. If you decide not to participate in this study, you will continue

with your routine treatment, and we encourage you to discuss other treatment options with your antenatal care provider or local doctor.

7 What are the possible benefits of taking part?

The Belly Bed is an investigational device. The true benefit of this investigational device used in the treatment of pregnancy-related pain is not known. It is possible that you may benefit from being in this study as a result of the Belly Bed. You may also be helping other patients with a similar problem benefit from the knowledge gained from your participation in this study. Potential benefits of the Belly Bed include, but may not be limited to, the following: a reduction in pregnancy-related pain, improved quality of sleep and improved quality of life. We cannot and do not guarantee or promise that you will receive any benefit from this study.

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

Any study of a new medical device or procedure may have unknown, as well as known, side effects, discomforts and risks. Every effort has been made to minimise the risks involved with this study, however, complications may occur.

The risks associated with this study include those risks associated with different sleeping position. The potential adverse events are arm numbness and surrounding muscle strain from side sleeping, and neck muscle strain from sleeping on the belly.

Regardless of whether you are randomised to the Belly Bed or your own bed, it is recommended that you sleep on your side during pregnancy (including the third trimester). Sleeping on your left side has shown to be the better side to sleep as sleeping on the left reduces the pressure on your circulation. It is not recommended that you sleep in the supine (on your back) position during pregnancy on any bed, including The Belly Bed.

Due to the design of The Belly Bed, if you are randomised to sleep on The Belly Bed you may be able to sleep comfortably in the prone position (on your stomach), with your belly in the belly cavity. As sleeping in this position is usually uncomfortable, due to the pressure caused by your belly pushing upwards, the researchers do not know if sleeping in this position may pose any risk to you or your baby.

One of the study team who is an obstetrician or midwife will provide you with advice on sleeping positions during the study.

In an effort to minimise all the risks mentioned above, the study team has been specially trained to perform the study-related procedures. In the event of any complication, appropriate treatment will be provided to you. This may include medical and/or surgical treatment.

For more information about risks and potential complications, please ask your antenatal care provider or a member of the study team.

9 What if new information arises during this research project?

During the course of the study you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the study or new alternatives to participation that might cause you to change your mind about continuing in the study. If

new information is provided to you, your written consent to continue participating in this study will be requested.

10 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the study team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study team about any changes to these during your participation in the research project. In consultation with your antenatal care provider and the study doctor, the study coordinator will explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

11 What if I withdraw from this research project?

Your participation in this study is completely voluntary. You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time. If you choose to participate, you have the right to withdraw at any time for any reason. If you withdraw from the study it will have no impact on your relationship with your doctor, antenatal care provider or *[insert institution],* your medical care or other services to which you are otherwise entitled.

The study doctor may withdraw you from participating in this study in cases where it is necessary to protect your health and safety, or in the event the study is terminated for any reason.

If you decide to withdraw from the project please notify a member of the study team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project the study doctor and relevant study staff will not collect additional personal information from you, 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 up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

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

- Unacceptable side effects
- The treatment device being shown not to be effective
- The treatment device being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personally identifying information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

The records of this study will be made available only to study doctors, physicians, midwives, nurses and study personnel responsible for evaluating your treatment. These records will be used only in connection with carrying out obligations relating to the study and will remain confidential at all times. Scientifically trained and properly authorised employees of local, national or international regulatory bodies and/or The Belly Bed Pty Ltd (the study sponsor) and their delegated representatives may also inspect these records.

All of the people identified in the previous paragraph are bound by rules of privacy and confidentiality not to disclose personally identifying information about you without your written permission, unless it is necessary to protect your rights or welfare (for example, if you are injured and need emergency care) or if required by law.

During this study a unique identification number will be used instead of your name to distinguish your records from the records of other patients participating in the study. Personal identifying information (such as your name, or hospital admission number) will be blacked out on all copied documents. All records will be stored in a locked room accessed only by the study doctor and research staff. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, The Belly Bed Pty Ltd, the institution relevant to this Participant Information Sheet, *[insert institution],* or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

The information obtained from you during this research study will be held by *[insert institution]* and the sponsor for 15 years. Your information will also be stored in a dedicated study database with limited and password protected access in OpenClinica Electronic Data Capture. The data will be retained for two years following (1) the date the investigation is completed or terminated, or (2) the records are no longer required to support a regulatory submission, or (3) as per national law requirements, whichever is longer.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project will be recorded in your health records.

In accordance with relevant Australian and New South Wales State privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

14 Compensation

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.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

- The Medical Technologies Association of Australia has set up a compensation process, with which the Sponsor, The Belly Bed Pty Ltd, of this research project has agreed to comply. Details of the process and conditions are set out in the *Medical Technology Association of Australia Compensation Guidelines*. In accordance with these Guidelines the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request.
- You may be able to seek compensation through the courts.

15 Who is organising and funding the research?

This research project is being funded by the Sponsor, The Belly Bed Pty Ltd. *[insert institution]* will receive a payment from The Belly Bed Pty Ltd for undertaking this research project.

16 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 <<*insert institution*>>

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.

17 Further information and who to contact

Who can I contact?

For further information or any problems or queries that arise during this study, or to report a possible research related injury, please contact:

Complaints

If you have any reason for complaint or concern about the study, or questions about your rights as a study participant, please discuss this with the investigators or contact <<*insert name*>> <<*insert institution*>> on <<*contact details*>>.

Participant Consent Form

Title	**A Feasibility, Randomised, Open-Label, Parallel Group to Evaluate the Safety and Efficacy of the Belly Bed in Reducing Sacroiliac Joint Pain, Lumbar Spine Pain, and Symphysis Pubic Pain Associated with Third Trimester Pregnancy**
Short Title	**The Belly Bed Trial**
Protocol Number	**TBB-CIP-01**
Project Sponsor	**The Belly Bed Pty Ltd**
Principal Investigator	*[insert PI]*
Location	*[insert institution]*

Declaration by Participant

- I have read the Participant Information Sheet *(Insert site version*) 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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[insert institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
- 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 study without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.

Name of Participant (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, Study Coordinator or delegated researcher

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

Name of Study Doctor, Study Coordinator or researcher

(please print) _____

Signature _____ Date _____

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

Form for Withdrawal of Participation

Title	**A Feasibility, Randomised, Open-Label, Parallel Group to Evaluate the Safety and Efficacy of the Belly Bed in Reducing Sacroiliac Joint Pain, Lumbar Spine Pain, and Symphysis Pubic Pain Associated with Third Trimester Pregnancy**
Short Title	**The Belly Bed Trial**
Protocol Number	**TBB-CIP-01**
Project Sponsor	**The Belly Bed Pty Ltd**
Principal Investigator	*[insert PI]*
Location	*[insert institution]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[insert institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant 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.