**Participant Information Sheet/Consent Form**

**Intervention and control group**

**Health/Social Science Research** -*Adult providing own consent*

Blue Mountains District Anzac Memorial hospital

**Project Title:** Does using a peanut ball during labour with an epidural affect birth outcomes? A pilot study

**Short Title:** Peanut ball’s effect on birth outcomes for women having an epidural during labour

**Coordinating Principal Investigator:** Associate Professor of Midwifery Virginia Skinner

**Associate Investigators:** Dr Robin Burr, Associate Professor Kenny Lawson,Justine Elliott, Sarah Cachia, Madeleine Simpson, Heather Reilly, Dr Wafa Al Omari, Dr David Campbell, Dr Biing Yin, Deborah Gaynor, Heather Borradale

**Location:** Blue Mountains Anzac District Memorial Hospital (BMADMH) Birthing Unit

**Part 1 What does my participation involve?**

**Introduction**

You are invited to take part in a research pilot study that examines the effects of using a peanut ball during labour if you have an epidural. Your contact details were obtained from the birthing unit midwife or from your expression of interest sent to Virginia Skinner.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. 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 local health worker.

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

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 involved in the research 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?**

We are conducting a study that is known as a pilot study and the main reason for this is to determine if there are any benefits for women using the peanut ball in labour with an epidural before we go on to do a larger main study. There is some evidence from other countries to show that using a peanut ball during labour whilst having an epidural does shorten the length of labour and increases the likelihood of having a normal birth, but there is no evidence in Australia and this pilot study is the first of its kind in Australia, as this is not usual practice. The peanut ball is shaped like a peanut and comes in three main sizes and is used during labour for a variety of reasons including positioning, assisting with the baby turning from a posterior position to an anterior position, reducing the length of labour and reducing the chance of having a caesarean section.

This research has been initiated by the researcher, Associate Professor of Midwifery Virginia Skinner.

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

As long as you are able to speak English or any other language, you are at least 36 weeks’ gestation, your baby’s head is in your pelvis and if you agree to participate in this study, and prior to any information being collected from you, you will be asked to sign the Participant Consent Form. You will be allocated into one of two groups- 1) using the peanut ball or 2) not using the peanut ball. The reason why we randomly allocate you into one of these two groups is firstly so that we are not biased in reporting the results and secondly, we can compare birth outcomes between the two groups. This way, we can determine if there are significant differences between the two groups and provide recommendations for further use of the peanut ball during labour if the outcomes are positive.

We are mainly interested in assessing your length of labour and what type of birth you have whilst having an epidural during labour. We are also interested in other aspects of your birth such as what position your baby is lying in, if you are side-lying or semi upright following insertion of your epidural, your baby’s condition at birth, whether you had stitches, other methods of pain relief during labour and if you were induced or augmented for your labour. These details will be provided by progress notes during your labour. Some other details will be collected including your age, education and country of birth.

1. *Information from maternity database*

We are very interested in obtaining information about the length of your labour and what type of birth you experience. We will obtain this information from the maternity database- E-Maternity following your birth. We will also collect other details about your labour and birth as outlined above.

1. *Online Surveys following your birth*

We will also ask you to complete two online surveys that we will send to you via email in the postnatal period up to six weeks following the birth of your baby that will take about 30 minutes to complete. If you have been allocated to the group using the peanut ball, one of the surveys will ask you to provide information on your thoughts about using the peanut ball during labour, if you thought that is was beneficial, if it was comfortable during your labour and the positions you used. If you have been allocated to either the group using the peanut ball or the group not using the peanut ball, we will send you a survey about your general health. If you do not respond to the first request to complete either of these online surveys, you will be sent the survey questionnaires a second time as a reminder ten days following the first.

There are no costs associated with participating in this research project, nor will you be paid.

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

This information sheet is for you to keep. If you consent to being involved in the study, please complete the consent form and email to V.Skinner@westernsydney.edu.au or you can give your consent form to the midwife in the birthing unit.

**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 care, your relationship with professional staff or your relationship with Blue Mountains Anzac District Memorial hospital.

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

There is some evidence from other countries to show that using a peanut ball during labour whilst having an epidural does shorten the length of labour and increases the chance of having a normal birth.

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

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

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

If you decide to withdraw from this research project, your information will not be included in this project and you can withdraw without penalty (please see withdrawal form at the end of this sheet).

**9 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 loss of employment or resources.

**10 What happens when the research project ends?**

If you indicate that you would be interested in final overall results of the study, please indicate yes or no in the designated space on the consent form.

**Part 2 How is the research project being conducted?**

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

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The information obtained by the online surveys will be able to identify your email and results of the surveys. This will be stored on an online survey repository, only accessible by the Coordinating Investigator and the research personnel, as it is password protected. The information will be stored on a password protected computer. Your confidentiality will be protected as the data will be de-identified and study participants will not be identifiable in any way. 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.

The personal information that the research team collect and use includes the survey information. Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

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, except with your express permission. All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

Please inform the research team member named at the end of this document if you would like to access your information. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**12 Complaints and compensation**

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

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

This research project is being conducted by Virginia Skinner, Kenny Lawson, Robin Burr, Justine Elliott, David Campbell, Biing Yin, Wafa Al Omari, Heather Reilly, Sarah Cachia, Madeleine Simpson, Deborah Gaynor and Heather Borradale. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**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 the HREC of Nepean Blue Mountains Local Health District.

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.

**15 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any further problems which may be related to your involvement in the project, you can contact the researcher on: (0408 427 612) or any of the following people:

**Research contact person**

For matters relating to research at the site at which you are participating, the details of the local of the local site complaints contact person are;

|  |  |
| --- | --- |
| Name | *Virginia Skinner* |
| Position | *Chief Investigator* |
| Telephone | *0408 427 612* |
| Email | *V.skinner@westernsydney.edu.au* |

**Complaints contact person**

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

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| Name | *Mary Brown* |
| Position | *Quality ManagerBMADMH* |
| Telephone | *4784 6590* |
| Email | *Mary.Brown@health.nsw.gov.au* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *Nepean Blue Mountains Local Health District Human Research Ethics Committee* |
| HREC Executive Officer | *Penny Mahairas* |
| Telephone | *02 4734 1998* |
| Email | *NBMLHD – ResearchOffice@health.nsw.gov.au* |

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**Consent Form -** *Adult providing own consent*

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**Location:** Blue Mountains Anzac District Memorial Hospital Birthing Unit

**Declaration by Participant**

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 future care.

I acknowledge that any regulatory authorities may have access to my medical records **specifically related** to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

I understand that I will be given a signed copy of this document to keep.

I would be interested in final overall results of the study – Yes No

My email and preferred contact details are: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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|  | Name of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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

**Form for Withdrawal of Participation -** *Adult providing own consent*

**Project Title:** Does using a peanut ball during labour with an epidural affect birth outcomes? A pilot study

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**Associate Investigators:** Dr Robin Burr, Associate Professor Kenny Lawson,Justine Elliott, Sarah Cachia, Madeleine Simpson, Heather Reilly, Dr Wafa Al Omari, Dr David Campbell, Dr Biing Yin, Deborah Gaynor, Heather Borradale

**Location:** Blue Mountains Anzac District Memorial Hospital Birthing Unit

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Nepean hospital.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by 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.

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|  |
|  | Name of Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.