**Participant Information Sheet - Version 3 - August 2016**

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| **Title** | ***Feasibility study to compare varying low-dose concentrations of Bupivacaine +2mcg/ml Fentanyl for the maintenance of labour epidural analgesia on delivery unit*** |
| **Investigator Name:** | Dr Matthew Drake, Dr Setareh Ghahreman, Dr Ee Mei Soo & Dr Morgan Edwards |
| **Address:** | Department of Anaesthesia – National Women’s Health (NWH), Level 9, Auckland City Hospital, Auckland |
| **Phone number:** | 09 307 4949 ext. 25026 |
| **Ethics number:**  | 15/STH/142 | **A+ number:** 6797 |

You are being invited to participate in a study looking at our epidurals for pain relief in labour. Whether or not you take part is your choice. If you don’t wish to take part you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what taking part would involve, what the benefits and risks to you might be, and whom to contact if you have any questions. We will also go through this information with you in person and answer any questions you may have. We will also go through this information with you in person and answer any questions you may have. If you agree to take part, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 3 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**What is the purpose of the study?**

 work out Some overseas hospitals already use lower doses of epidurals than the dose that is currently used at National Women’s Health, and we are looking to improve our epidurals here. We know that epidurals work very well for pain relief in labour and have very few problems, but women who have an epidural can sometimes develop heavy legs and numbness in labour. Very rarely, this can make it more difficult to move around in labour and to push. We would like to check if we can provide the same pain relief effect with a lower amount of medication in our epidurals, which might be better for women and reduce these problems.

**What will my participation in the study involve?**

Once you have had your epidural sited and are feeling more comfortable, we will approach you to discuss the study and whether you would like to be involved.

At this stage of the study, we are comparing two different strengths of the same medicine to assess the pain relief it gives and any side effects it causes. By taking part in this study, your epidural will contain one of the two strengths of epidural medicine doses we use for labour. We will check your epidural at various time points during your labour to see how good your pain relief is and whether you have any weakness in your legs. Much of this will be done by your midwife as normal for a labour epidural. She will ask you to score how comfortable you are out of 10 and check how much movement you have in your legs. After you have delivered your baby, one of the doctors listed overleaf will visit you on the ward or, if you have left NWH, contact you by telephone. This will be to ask you what you thought of your epidural, whether you were comfortable and if you noticed any problems. This follow-up should take less than 3 minutes in total.

**What are the possible benefits and risks of this study?**

We hope that this study will confirm what we already know from other studies – that we can use less medication in an epidural for effective pain relief in labour. If this is the case at NWH, then we will lower the strength of the epidural medication we give, which might mean women are able to move around more in labour, have less weakness and be more satisfied with their epidural pain relief.

There are very few risks from taking part in this part of the study, beyond the normal risks for an epidural which will have been explained to you by the anaesthetist who put in your epidural. There is a possibility that the lower dose of epidural medication might be less effective for labour pain relief, but this is very unlikely. All normally-available pain relief will be provided should you require it. We will be checking your epidural very closely during your labour and any problems with your pain relief will be quickly picked up and treated.

**Who pays for the study?**

This study is being paid for by the hospital. By taking part you will not be required to pay anything towards the study.

**What if something goes wrong?**

If you were injured in this study, which is unlikely, 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 automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assists in your recovery.

**What are my rights?**

This study is voluntary, which means that it is your choice if you take part or not. If you don’t wish to take part you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

All information collected about you is confidential and will only be used for the purpose of this study. You have the right to access any of the information collected about you as part of this study.

**Whom do I contact for more information or if I have any concerns?**

Please feel free to contact Dr. Matthew Drake, Dr. Setareh Ghahreman, Dr Ee Mei Soo or Dr Morgan Edwards if you have any further questions at the above phone number.

This study has received ethical approval from the New Zealand Health and Disability Ethics Committee and the Auckland District Health Board Research Review Committee.

If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an Independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ Wide): 0800 555 050

Free Fax (NZ Wide): 0800 2787 7678 (0800 2 SUPPORT)

Email: advocacy@hdc.org.nz

If you require Māori cultural support please talk to your whānau in the first instance.

Alternatively, you may contact He Kamaka Waiora (Māori Health Gains Team) by telephoning the team leader on phone 307 8968 or 021 924 032

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by phoning 09 4868920 ext 3204