Evaluation of Success in Neuraxial Block Placement between using Palpation of Landmark versus Pocket-Size Handheld Ultrasound (U/S) Method

Informed Consent Form to Participate in Research
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INTRODUCTION
You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a pregnant woman who is electing to receive an epidural and/or spinal block to treat your labor pain or for cesarean delivery. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to determine the difference between the 2 methods of more accurately locating the site of needle insertion to quickly and successfully complete the epidural and/or spinal block for you. One usual practice and method is by palpation of your spine and hip bone (iliac crest) as landmark and the other method being studied is to apply a small ultrasound probe to the surface of the skin on your back to obtain an image of your back.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Approximately 180 patients will take part in this study. In order to identify the 120 subjects needed, we may need to enroll as many as 180 because some people will not complete the study.

WHAT IS INVOLVED IN THE STUDY?
The study will be discussed with you after you are admitted to the Labor and Delivery Unit or during your preanesthesia assessment at Novant Health Forsyth Medical Center to deliver your baby either vaginally or by cesarean delivery. All of your questions will be answered. If you agree to participate you will be asked to sign this form. A signed copy of this form will be given to you and a copy will be placed in your permanent medical record.

Inclusion criteria including BMI >30. Exclusion criteria include absolute contraindications for neuraxial block. After signed informed consent, you will be randomized into one of two groups like drawing a number randomly from a bag - : Group P (Palpation) and group R (Rivanna Accuro ultrasound (U/S)). When the subject is ready for the epidural or spinal procedure, the location for epidural or spinal needle insertion will be identified by both palpation method using conventional landmarks (tip of the spine and iliac crest - which is the top of the hip), and with Rivanna Accuro U/S device method which gives an image of the bony structure of the back. The ultrasound probe will be applied gently on the surface of skin of the back to located where the midline of the back is, which takes about 1-5 minutes (typically 1-2 minutes).

Then if you are in group P, the epidural or spinal block will be performed as in usual method using the needle insertion site identified with palpation method. If you are assigned to group R, the needle insertion site will be the site identified by the Rivanna Accuro U/S device. The rest of the procedure remains the same as in the usual practice for placement of the block regardless of patients enrolled in this study or not. After placement of block, the usual standard dose of medication will be administered as in usual manner for patients regardless in this study or not. The usual practice of the block placement, management and medication used would have been already explained to you by your anesthesia provider before obtaining consent for this study.

HOW LONG WILL I BE IN THE STUDY?
You will be in the study for the length of your labor analgesia or cesarean delivery. You can stop participating at any time. There are no known consequences of withdrawal from this study.

WHAT ARE THE RISKS OF THE STUDY?
There are no additional risks to participating in this study. If you elect to participate then then it is predetermined that you will receive one of the 2 methods to determine initial site of needle insertion for placement of the block. If you elect not to participate, then the usual method of palpation of landmarks will be used to place your epidural anesthesia.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future and improve the practice and accuracy of successful epidural and spinal block.

WHAT OTHER CHOICES ARE THERE
Your alternative is to not participate in this study and the usual method of palpation of landmark will be used instead of ultrasound. Your provider may still choose to use the ultrasound method if he/she deems it necessary or helpful but no additional measurement information will be used for research or comparison purposes.

WHAT ABOUT MY HEALTH INFORMATION?
By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, photographs/videotapes/audiotapes and information from study visits, phone calls, surveys, and physical examinations. Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. Some of the people, agencies and businesses that may receive and use your health information are investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University School of Medicine ; representatives from Novant Health-Forsyth Medical Center; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries. Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be

covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care. When you sign this consent and authorization form, you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Dr. Peter H. Pan
[redacted]

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE THE COSTS?
There are no costs to you for taking part in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?
You will not be compensated for your participation in this clinical research study.

WHO IS SPONSORING THIS STUDY?
This study is being sponsored by Wake Forest School of Medicine Department of OB Anesthesiology. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?
Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions, or because the entire study has been stopped. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Pan, or a member of his research staff at [redacted] or after hours you should call [redacted]
The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact either the IRB manager of the Novant Health Forsyth Medical Center IRB at [redacted] or the Chairman of the Wake Forest School of Medicine IRB at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES
I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered.

Subject Name (Printed):_____ Date: _____

Subject Signature: _____ Time:_____

Person Obtaining Consent: _____ Date/time:_____