PARTICIPANT INFORMATION AND CONSENT FORM

ROYAL MELBOURNE HOSPITAL

Quality Assurance Project: Comparing the use of a needle guidance device with free-hand technique in performing out-of-plane ultrasound-guided intervention procedure on a phantom model

Investigators:

Principal Researcher:	Dr Patrick Tan
	(03) 93427540
	p.tan28@gmail.com
Associate Researchers:	Dr Irene Ng
	Dr Charles Kim
	Dr Graham Lethbridge

This Participant Information and Consent Form is 4 pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this quality assurance project. Participation is voluntary and you may decline if you wish. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your acceptance or refusal of this invitation will not be disclosed to other departmental staff (other than the other researchers for the purposes of avoiding duplicate invitations).

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a colleague. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose

Regional analgesia and vascular access performed under ultrasound guidance has rapidly become a new and essential part of safe modern anaesthesia practice. The skills are however difficult to acquire as there is a lot of practice required to achieve good hand

eye coordination and allow for the procedure to be performed in a timely and efficient manner.

The purpose of this project is to compare the effectiveness of the CIVCO Accusite (out-of-plane) Needle Guidance System when performing an ultrasound-guided procedure.

The basic principle of using the CIVCO Accusite (out-of-plane) Needle Guidance System is to allow for the needle to be constantly kept in middle of ultrasound beam, and thus always accurately hit a target that is centralised on the ultrasound screen. In a recent study conducted at Royal Melbourne Hospital, an in-plane model of this needle guide was shown to be superior to the free-hand technique for in-plane procedure using a phantom model. However, there is currently no study comparing the out-of-plane needle guide with free-hand technique.

We wish to determine the effectiveness of the guide when used in our department by a group of anaesthetic residents, registrars and consultants with different levels of clinical experience on a phantom model.

A total of 30 people will participate in this project.

This trial has been initiated by investigator Dr Patrick Tan, Anaesthetic Registrar at the Royal Melbourne Hospital

You are invited to take part in this research project because you are an accredited anaesthetic trainee/consultant. This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

3. Procedures

Participation in this project will involve

- Collection of your personal and medical training information, such as year of training, number of procedures previously performed with ultrasound. This information will be de-identified at collection. All results will be kept anonymous.
- Firstly, you will receive a presentation giving an explanation of the use of the needle guide and the anatomy of the specimen. Then you are permitted to practice needling technique on a Phantom Gel with and without the needle guide for 5 minutes.
- Following this introduction and practice, you will then be asked to perform the procedure on the phantom model with and without the needle guide in the order depending on the randomization.
- We will record information related to the time taken to perform the procedure, the number of insertion attempts and the number of times an incorrect target is hit. We will also ask for your satisfaction score at the end of the procedure.
- Your time commitment is expected to be no more than half an hour

4. Possible Risks (if applicable)

You will be asked to perform an ultrasound-guided procedure in a psyllium mucilloid fiber (Metamucil) and gelatin phantom model both with and without the needle guide, after

usage instruction. You will be using blunt (non cutting needles) with gloves, to reduce chance of injury, however it could be possible to suffer injury from the needle, (but no chance of exposure to human blood borne disease). These risks are lower than you would expect to face in your usual professional practice. You will also be asked a satisfaction score following the completion of the procedure.

5. Privacy, Confidentiality and Disclosure of Information

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. In any publication of the results of the project, information will be provided in such a way that you cannot be identified.

Data collected about you will be labelled with a unique study number, not your name or trainee number and documents will be stored on paper and in password protected computer files, along with all research-related document in a locked office in the Department of Anaesthesia and Pain Management at the Royal Melbourne Hospital for 5 years from the date of publication of the results of the study before being deleted. Only the principal investigator and the co-investigators will be able to use the information as stated in this document.

Representatives from the Melbourne Health Human Research Ethics committee may inspect the study records, for the purpose of verifying information and checking study procedures. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named below if you would like to access your information

6. Results of Project

On completion of the project, a written plain English summary of the results will be made available to you upon request.

7. Other Issues

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

Name: **Ms Jessica Turner**

Position: **Manager Human Research Ethics Committees, Melbourne Health**

Telephone: **(03) 9342 8530**

You will need to tell Ms Turner the number or name of the project (refer to page 1).

Consent:

I freely agree to participate in this project according to the conditions in the Participant Information.

Participant's Name (printed) ……

Signature …… Date

Investigators Name (printed) …….

Signature …… Date