**Patient Information Sheet**

**Does cadaver simulation training offer best clinical performance behaviour during ultrasound guided regional anaesthesia?**

***Or: Does practice on a cadaver simulator help anaesthetists perform better on patients***

**We would like to invite you to take part in this research trial/study**

Briefly and using understandable, age appropriate, language.

What are you proposing? Why are you doing this research? What is already known? How many will be involved in the trial/study and where? Why am I being invited?

MANDATORY TEXT

Before you decide whether or not to participate, we need to be sure that you understand firstly why we are doing the trial/study and secondly what it would involve if you agreed to take part. We are therefore providing you with this information. Please take time to read it carefully, ask any questions, and, if you want, discuss it with others. We will do our best to explain and provide any further information you may ask for now or later. You do not have to make an immediate decision.

MANDATORY TEXT

This trial/study is being sponsored by the University of Dundee and NHS Tayside. It is being funded by the National Institute for Academic Anaesthesia. The study has been organised by Professor Graeme McLeod and Dr Joanna Lynch, Anaesthesia; Professor Jean Ker, Medical Education and Professor Tracey Wilkinson, Anatomy.

**If I take part what will it involve?**

You have agreed already with the surgeon and anaesthetist at the pre-assessment clinic to have shoulder surgery and a nerve block in the neck beforehand to reduce pain after surgery. This is called an interscalene block. We will guarantee you will receive the care discussed with these doctors.

In this study we want to investigate the training of anaesthetists before encountering patients. This is called simulation training. We want to train anaesthetists on two different types of simulator and find out if training on one or the other makes a difference when performing the procedure on patients.

The advantage of this study is that all anaesthetists will receive standard training which involves a lecture, ultrasound imaging of student volunteers and needle practice on a piece of plastic called a “blue phantom”. The anaesthetists will then be divided into two groups that offer extra training. The first will receive extra needle insertion training on a piece of pork with embedded tendon that looks like a nerve on ultrasound. The other group will get training on a type of soft cadaver that is unique to Dundee. The cadaver is soft, elastic and life–like and provides the best simulation of needle insertion and surgery anywhere. This way we will find out which simulator is best for training anaesthetists in nerve blocking techniques.

The anaesthetists will be videoed and wear special glasses that monitor their eye movement. This is called eye tracking. It is very sensitive instrument that gives an idea of where the anaesthetist is looking.

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

The principal benefits of participation are:

* You will receive a nerve block by an anaesthetist who has had training over and above standard training
* All nerve blocks will be video recorded and supervised by an expert consultant anaesthetist
* The expert anaesthetist will step in and take over the block if necessary. This is normal practice in a teaching hospital
* You will participate in a study that is attempting to change the way doctors are trained, by using a simulator and increasing skill levels before treating patients
* We think that training in a safer, simulated environment has the potential to improve patient safety, improve clinical performance and patient outcomesYou cannot guarantee any specific benefits – make this clear. It’s reasonable to note that research does deliver wider benefits to society/others with a similar condition and some indirect benefits might be foreseeable.

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

The alternative is that:

* You will receive your nerve block from either a consultant or trainee anaesthetist under supervision. We cannot guarantee that the trainee has had cadaver simulator based training.

**Detail all significant risks – medical, confidentiality, psychological – and both likelihood and severity of adverse things happening. egs**

**• Side effects of interventions**

**• Discovery of IF**

**• Personal data made public**

# **Do I have to take part?**

MANDATORY TEXT

It is up to you to decide. Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you.

**Will my personal information be kept confidential?**

Identifiable information about you and your collected study data will be stored locally and designated members of the research team will have access to this information.

For data management purposes, your anonymised coded study data will be securely stored on a password-protected database(s) in the University of Dundee and at Optomize Ltd, a psychology research company which is analysing the data. Specified members of the data management team will also have access to your identifiable information.

Your data will be archived securely for five years after the end of study, after which it will be destroyed. Identifiable information about you will not be published or otherwise shared. Your anonymous study data may be shared with other researchers world-wide.

**What if something goes wrong?**

MANDATORY TEXT

If you have any concerns about your participation in the study you have the right to raise your concern with a researcher involved in conducting the study. If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However you have the right to raise a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Complaints and Feedback Team

NHS Tayside

Ninewells Hospital

Dundee DD1 9SY

Freephone: 0800 027 5507

Email: feedback.tayside@nhs.net

**Insurance**

MANDATORY TEXT – FOR CTIMPs

Tayside Health Board is sponsoring the trial/study. **If NHST the co-Sponsor/Sponsor**Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which provides legal liability cover of NHS Tayside in relation to the trial/study.

**If NHS Tayside a Site – or delete**

As the study involves University of Dundee staff undertaking clinical research on NHS Tayside patients, such staff hold honorary contracts with Tayside Health Board which means they will have cover under Tayside’s membership of the CNORIS scheme.

**If other NHS Boards in Scotland are Sites – or delete**

Other Scottish Health Boards are participating as trial/study sites and they also maintain membership of CNORIS to cover their liability in relation to their conduct of the trial/study.

**If NHS Trust in England are Sites – or delete**

**If NHS Trust in Wales are Sites – or delete**

**MANDATORY TEXT**

**Who has reviewed this trial/study?**

MANDATORY TEXT

This trial/study has been reviewed and approved by the North East Committee on Medical Ethics who are responsible for reviewing research which is conducted in humans and who has raised no objections.

Detail which NHS (or other) REC has approved the trial/study.

Detail how patients and the public been involved in the trial/study

**Contact details for further information.**

Insert email and telephone number for appropriate research staff at Site

You may also choose to provide contact details for someone unconnected to the trial/study who can provide expert independent advice

MANDATORY TEXT

Thanks for taking time to read this information and for considering participating in this trial/study.

If you would like more information or want to ask questions about the trial/study please contact the trial/study team using the contact details above. You can contact us Monday – Friday between 09:00-17:00 at 07974 440 848