**Participant 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 will be invited to attend the Centre for Anatomy and Human Identification in Dundee for UGRA training. This will last approximately half a day. You will first be asked to complete simple tests that will give us a baseline measure of your psycho-motor and visuo-spatial abilities. Thereafter, you will be trained in interscalene block using a variety of methods. These will include basic training (lectures, volunteer scanning, and needling skills on a blue phantom or pork specimen), additional skills training on the soft embalmed cadaver, or more intense supervision and feedback using proven educational methods. We do not know what sort of training you will receive. If you agree to participate and come to Dundee, you will be randomised to one of the aforementioned groups.

Potential participants need to know what they are being asked to give consent to, so make it clear including elements additional to standard care.

Consider needs of specific groups e.g. adults with incapacity, children/young people, vulnerable people.

Consider specific issues eg

• Consent process - refer to TASC SOP07

• Screening and exclusion

• Randomisation and blinding, if appropriate

• No. and location of trial/study visits

• No. and type of trial/study interventions

• Duration of involvement – including clinical phase and FU

• Involvement of participant’s GP/ other healthcare practitioner including Incidental Findings

• Tissue samples – storage, sharing and future use

• Research data – storage, access, sharing and future use.

• Expenses and payments?

• Genetic research? – therapeutic or diagnostic

• Exposure to ionising radiation?

• What if relevant new information becomes available?

• Withdrawal process – consider FU visits, data and tissue

• Loss of capacity - refer to TASC SOP07

• What happens when the research trial/study stops?

• What will happen to the results of this trial/study?

• What if relevant new information becomes available?

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

The principal benefits of participation are:

* The opportunity to train on the soft embalmed cadaver, the most life-like simulator of regional anaesthesia
* The chance to improve skills before intervening on patients
* To develop techniques in a safe environment that may improve 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 do not have the opportunity to train on the soft embalmed Thiel cadaver
* Do not have the opportunity to be supervised by leading expert regional anaesthetists

**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 East of Scotland 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