Emergency Department
Ear Acupuncture
(EDEA)

A research project led by Professor Andrew Jan

Why are we doing this research?

In this study we are trying to see whether ear acupuncture along with standard pain medications offers better pain relief than standard pain medicines alone. Currently some of our pain medicines cause side-effects in both the short and long term. Acupuncture has a low side effect profile but is not proven to work for acute pain. This study hopes to show that acupuncture is effective for pain relief and that less amounts of strong pain medicines are used.

Do I have to take part?

No, you don't have to take part. It's your choice and if you don't wish to enter the trial, you don't have to. If you choose not to enter the trial, there will be no repercussions and you will receive our high standard of care.

What are the main steps in the study?

You will be asked to enter the trial and then randomly assigned to one of the three pathways of the trial. All three routes will receive our usual best practice pain medications. However, one group, in addition to the usual pain medicines, will receive ear acupuncture with needles. The second group will receive ear acupuncture with an electric device in addition to usual care, and the third will have best practice pain medicines alone. However, because this is a trial, all groups will have small ear tapes applied to prevent the nurses knowing which pathway you are in. The nurses will record your pain scores for 2 hours and then carry out a very brief questionnaire about satisfaction and any adverse effects.

What will happen to information about me?

We will keep any information confidential and securely stored. All of the collected data will be non-identifiable. Seven years post publication the data will be destroyed.

What possible benefits might I get by taking part?

You'll might get to try a new mode of pain relief on top of usual pain medicines. A big benefit is that you will feel good about contributing to research on pain medicines and acupuncture. Trials such as these can make pain relief both more effective and safer for the future.

What risks do I run by taking part?

Acupuncture has a reputation of having a low side effect profile but like all medical interventions there is always a possibility of a side effect albeit a very small one. The biggest risk to avoid is infection, so we have taken steps to minimise this by wiping the ear with alcohol prior and removing the needles at 2 hours rather than 3 days. Acupuncture needles can hurt a little and have minor bleeding either on

insertion or removal. The electric acupuncture device is also safe but to be very safe we won't be directly applying it to the skin or patients with pacemakers.

Will the results of the trial be published?

We intend for the study results to both be published in a scientific journal and presented at scientific meetings. You will be notified of publications and stories on this research via the trial website: www.edeatrial.com.au

Consent form

I have been given information about *Emergency Department Ear Acupuncture* and discussed the research project. I have been advised of the potential risks associated with this research, including minor pain and bleeding. I have had an opportunity to ask any questions I may have about the research and my participation. I understand that my participation in this research is voluntary; I am free to refuse to participate; and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect my pain management or how I am treated in any way.

If I have any enquiries about the research, I can contact Andrew Jan (Ph. 94389110 or via website) or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact Gorette De Jesus, Human Research Ethics Executive Officer (Ph. 93826940).

I understand that the data collected from my participation will be used for publication, and I consent for it to be used in that manner.

By signing below, I am indicating my consent to participate in the study.

Signed: _____ Date: _____

Name (please print): _____