Dear Participant,

Re: Investigating upper limb tourniquet pain: The ReTAP study

We would like to invite you to take part in a research project. This letter provides some information to help you decide whether to do so. Please take time to read this information carefully and discuss it with friends, family or your GP if you wish. If there is anything that you do not understand, or if you would like more information, please ask us. Please take time to consider whether you wish to take part.

What is the purpose of the research?
The goal of this research is to acquire new knowledge about the pain associated with an upper limb tourniquet used for local anaesthetic operations. This requires research on humans and involves the application of a tourniquet (tight pressure) around the upper arm, as would be done for patients requiring hand surgery. The tourniquet used is very similar to that used for measuring blood pressure, although would need to be left on your arm for longer whilst we ask you to rate your pain along a 100mm line. It is safe to interrupt the blood supply to your arm in this way for 1 hour without deflating the tourniquet, although the maximum time you might wear a tourniquet in this study would be a single instance of not more than 30 minutes. If you would like the tourniquet to be removed for any reason we can remove it immediately at any time. This technique has been approved by the Central University Research Ethics Committee (CUREC).

Why have I been invited?
You have been invited to take part in this research because you are healthy, at least 18 years old and fluent English speaking.

Do I have to take part?
No. It is up to you to decide if you want to take part in this study. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to take part, we will ask you to sign a consent form and give you a copy for you to keep. However, you would still be free to withdraw from the study at any time, without needing to give a reason. This would not affect the standard of care you would receive. If you are a student at the University of Oxford or Oxford Brookes, there would be absolutely no academic penalty if you decide you do not want to take part in this study, or if you decide to withdraw at any point. If you have private health insurance we advise you to contact your insurer to ensure that participation in this study does not contravene the terms and conditions of your policy.

What will the study involve?
For this study you will first be asked to lie down and breathe either oxygen or normally constituted air through a mask for 3 minutes. We will also measure your blood pressure and pulse non-invasively (using standard automatic blood pressure cuff and machine and pulse oximeter probe placed on a finger) on the other arm. Then a tourniquet (tight pressure) will be applied to the test arm at the point of maximum circumference and inflated to 250mmHg, as would be done for patients requiring hand surgery. We will ask you at two minute intervals to rate the pain in your arm by drawing a line on a 100mm visual analogue scale line. The tourniquet will either be removed immediately at your request or after a maximum of 30 minutes. You may experience some tingling and increased pain in the first few minutes after tourniquet removal. Your hand may become very pink and feel weak for 5-10 minutes. These are all temporary and entirely normal symptoms due to reperfusion of the arm. All symptoms should resolve within 15 minutes of tourniquet release. We would like to continue measuring pain, blood pressure and pulse for 15 minutes after tourniquet deflation.

Pain is an experience that is strongly influenced by various factors, including thoughts and emotions. In order to understand the complex nature of pain perception, you may be asked to perform additional computer-based or
paper and pencil tests. You may also be asked to complete questionnaires asking, for example, about your lifestyle, experiences, or mood.

If you agree, the total time taken to complete this study will not be more than 1 hour. There is an area in our facilities where an accompanying person can wait. On arrival, one of our research team will meet you to describe what is to be done and answer any questions you may have. We would also ask you to sign a consent form, of which you would be given a copy for you to keep.

**Are there any risks in taking part in this study?**
Tourniquets are used daily in medical practice. Patients and participants who have worn an upper limb tourniquet for 30 minutes report a temporary increase in pain, strange sensations and loss of grip strength for the 5-15 minutes following removal of the tourniquet. These symptoms usually resolve within 15 minutes. There has been one reported instance of a reduction in grip strength for the 24-48 hours following a tourniquet. Rarely, damage to the nerves in the arm and bruising of the skin under the tourniquet have been reported with improper application of tourniquets (application that did not conform to the AORN guidelines for safe tourniquet use). Only senior investigators, who are fully qualified doctors trained to apply the pneumatic tourniquet safely and as per AORN guidelines will be fitting the tourniquet cuffs during testing. This research method has been ethically approved by CUREC.

**Are there any benefits from taking part in this study?**
There will not be any direct benefits to you directly in this study. It is hoped that the results from this research will help us to identify better ways in which to conduct hand surgery.

**Who has reviewed this study?**
All research studies are checked by an Ethics Committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by and received ethics clearance through the University of Oxford Central University Research Ethics Committee (CUREC).

**Who is organising and funding the research?**
This research has been organized by the foundation Doctors in Plastic Surgery and is self-funded, with equipment supplied by Oak Medical Services.

**Who will know that I am taking part in this research?**
Only the researchers of this study. Any information collected about you during this study would be kept strictly confidential. Any data (including questionnaire answers) will be anonymised with a code so that the results could not be linked back to you. All the data is kept on protected computers and any paper information (such as your contact details) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team. Any personal information about you would be destroyed at the end of the study. Sometimes, new methods to analyze data become available after a study has ended. Therefore we would ask for your permission to use your anonymised data in future studies, and to share data, such as your anonymised data, with other researchers inside the European Union.

**What if something goes wrong?**
The University has arrangements in place to provide for harm arising from participation in the study for which the university is the Research Sponsor. If you have any concerns about any aspect of this study, please contact the Principal Investigator [Natalia White, 07792 994968] who will do their best to answer your questions. If you remain unhappy, and wish to make a complaint, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 857 939 or the head of CTRG, Heather House, email heather.house@admin.ox.ac.uk.

**What if I have further questions?**
Please contact Natalia White on 07792 994968 or Natalia.white@hotmail.co.uk who will happily answer any further questions you may have.

Yours truly,

Natalia White, Thomas Dobbs, George Murphy and Khurram Khan