

## Participant Information Sheet

### Title: The Surgery Compared with Radiofrequency Ablation for Partial Wrist Denervation (SRAPiD) Trial

Investigators: Abhinav Aggarwal, Peter Scougall, Damian Ryan, Richard Lawson, Sebastian Fung, Ashwin Aggarwal

**Participant Selection and Purpose of Study**

You are invited to participate in a study investigating different treatments of end-stage wrist arthritis. Though fusion of the wrist is effective in reducing pain, there are significant losses in range of motion and potential complications relating to healing or hardware. Partial wrist denervation, instead, can be used to manage chronic pain whilst still preserving baseline range of motion. It has shown to have high levels of patient satisfaction and to be effective in improving pain and strength.

Partial wrist denervation has traditionally been performed as a surgical procedure, which involves a small incision and removing the small nerves in the wrist. Recently, a technique using ultrasound guided heat ablation through the skin has instead been described. This avoids the risks of surgery and can be done on an outpatient basis. The limited data thus far show similar benefits to surgery, however, it is still an emerging technique without a direct comparison to surgery.

This study is therefore designed to compare the effectiveness of partial wrist denervation through surgery or through ultrasound guided heat ablation.

**Who is carrying out the study?**

The study is a collaborative effort involving hand surgeons (AA, PS, DR, RL) and an interventional radiologist (SF) across multiple hospitals in Sydney.

**‘What if I don’t want to take part in this study, or if I want to withdraw later?’**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

**Description of Study and Risks**

Your hand surgeon will explain the study and the different treatment groups. If you decide to participate, the treatment group you are assigned to will be randomised. No significant risks or benefits have been identified in this study.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. Your involvement in the study will have no impact on the management you are currently receiving, or will receive in the future.

**Confidentiality and Disclosure of Information**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or except as required by law. If you give us your permission by signing this document, we plan to use the data collected to form a scientific report that may be submitted for scientific publication. In any publication, information will be provided in such a way that you cannot be identified.

**Financial Costs**

It is not anticipated that you will incur any additional costs if you participate in this study. You will not receive any payment for participation in this study.

**Your Consent**

Your decision whether or not to participate will not prejudice your present or future treatment or your relationship with your healthcare provider or any other institution cooperating in this study*.* If you decide to participate, you are free to withdraw your consent and to discontinue your participation at any time without prejudice.

If you have any questions, please feel free to ask. If you have any additional questions later, the principal researcher (Abhinav Aggarwal) will be happy to answer them. He may be contacted at info@handwrist.com.au.

**You are making a decision whether or not to participate. Your signature on the consent form indicates that, having read the information provided above, you have decided to participate.**

Complaints may be directed to the Research Office, South Eastern Sydney Local Health District (Email: SESLHD-RSO@health.nsw.gov.au, Phone: (02) 9382 3587)

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.