PARTICIPANT INFORMATION STATEMENT ADDENDUM

Title	Effect of combined conservative therapies on clinical outcomes in patients with thumb base osteoarthritis: a randomised, controlled trial (COMBO)
Short Title	The COMBO study
Project Sponsor	The University of Sydney
Principal Investigator	Professor David Hunter
Associate Investigators	Anne Wajon, Ed Riordan, Kai Fu, Leticia Deveza, Ray Jongs, Sarah Robbins, Vicky Duong and Win Min Oo

Why am I being contacted?

You are being contacted because you participated in the COMBO study for the base of thumb osteoarthritis sometime between 2016 and 2018.

We would like to kindly request your consent to make your data available for future studies and share it with other researchers around the world. Since this research was publicly funded, it is expected that the data is made publicly accessible to others. Your confidentiality will always be kept, and only the investigators of this study will be able to re-identify your data.

We can be more confident with our findings if we can replicate them in other populations. Additionally, the more people we have in a combined database, the easier it is to identify the characteristics of people that are more likely to benefit from the treatment.

Signing this consent is completely voluntary. Your decision about whether to sign it will not affect your current or future relationship with the researchers or anyone else at The University of Sydney or Royal North Shore Hospital.

Will I be informed of the study results?

We have recently finalised the data collection for all participants, and we are currently analysing the data. As soon as we complete the analyses, we will send you a lay summary containing our main findings.

Data Access and Data Sharing

All investigators will have full access to the complete final dataset. The data will be stored in a re-identifiable format to ensure confidentiality.

We will keep the information we collect for this study, and we may use it in future projects related or not to this project. By providing your consent, you are allowing us to use your anonymised information in future projects. We don't know at this stage what these other projects will involve. These future projects will seek ethical approval before using the information from this study.

Three years after we perform the study close-out, we will publish all collected data in a data repository to share it with other researchers around the world. All information published will be de-identified, and it will be impossible for anyone, besides the investigators, to identify your data.

Study Record Retention

In compliance with the NSW State Records Act, the archiving period for clinical research records will be 15 years (NSW supplement to the National Statement, section 3.3.11). After this period, the electronic files will be deleted. The Information Technology (IT) department will be involved to ensure the deletion is complete and files are not retrievable from any source. The paper forms will be destroyed after this period being disposed of in confidential bins located at the RNSH.

e-PARTICIPANT CONSENT FORM (REDCap)

Participant's declaration

- ✓ I have read the Participant Information Statement.
- ✓ I have had the opportunity to ask questions, and I am satisfied with the answers I have received.
- ✓ I freely agree to make my anonymised data available for future research projects, to share it with other researchers and to be publicly available after three years from study close-out, as described.
- ✓ I understand that I am free to withdraw my data from being share without affecting my future care.
- ✓ I understand that I will be given a copy of this document to keep.

Your full name: _____

Signature: _____ Date: ____/____/_____