

## **Project Title: Pilot Study of Remote Health Status Questionnaire Completion by Mobile Phone in Patients with Osteoarthritis**

**Principle Investigator:** Prof Nicholas Bellamy, CONROD – Director, The University of Queensland

### **Primary objective of this study:**

This study is designed to investigate, the challenge of capturing information via a mobile phone. In the twelve day study a mobile phone based version of a well-established osteoarthritis symptom severity questionnaire will be used.

### **Overview of the study**

This study will be based at the Centre of National Research on Disability and Rehabilitation Medicine (CONROD) located in Herston, an inner northern suburb of Brisbane.

Twelve (12) people with osteoarthritis of the hip or knee will be invited to participate in this study. These participants will need to meet the criteria outlined below to be eligible to be invited to participate in the study and will be required to sign a consent form an example of which is attached.

Upon complete of the consenting process participants will receive an orientation to the questionnaire on the mobile phone. Briefly, this will involve a one-on-one information session on how to use the mobile phone, followed by a “dummy-run” (supervised) and finally a “test-completion” (unsupervised) to make sure that the participant has understood the procedure to be followed. This information session will be scheduled to take place at a time and place convenient to the participant.

The participant will then be sent away with the mobile phone and will receive text message reminders to complete the questionnaire on Day 3, Day 6, Day 9 and Day 12 of the study. During the study period, participants will have access to a “hotline” at CONROD in case they need assistance with the phone.

For participant convenience research staff will visit them at home following the final visit to collect the phone and also to supervise the patient’s completion of a final questionnaire-based interview about their experience using the mobile phone to complete the osteoarthritis questionnaire.

**PLEASE CHECK YOUR ELIGIBILITY TO REGISTER BY TICKING THE APPROPRIATE BOXES BELOW**

You are eligible to register your interest to participate in the study if you meet all of the following criteria:

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- You reside within ~50kms from Brisbane
- You are aged between 30 to 90 years of age
- You have been diagnosed with osteoarthritis of the knee or hip
- This diagnosis has been confirmed by an X-ray
- You speak English fluently
- You are willing to provide your written informed consent

You are NOT eligible to register your interest to participate in the study if you have any of the following:

- If you have , or have ever had, gout or episodes of pseudogout in your knee or hip
- If you have, or have ever had, rheumatoid arthritis or psoriatic arthritis
- If you are scheduled for a revision of surgery following a previous partial or total hip or knee arthroplasty
- If you are undergoing hip or knee arthroplasty for a condition other than osteoarthritis
- If you have had prior experience with completing the m-WOMAC<sup>®</sup> NRS3.1 Index arthritis questionnaire on the mobile phone

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**TO CONFIRM YOUR INTEREST IN PARTICIPATING IN THIS STUDY**

If you have read the information within this pack and meet the criteria to participate and would like to register your interest please contact Professor Nicholas Bellamy or Professor Bellamy's assistant, Chesne McGrath on 07 3365 5558. Please register your interest prior to 15 November 2009.

Please note, Arthritis Queensland is not involved in conducting this study and is unable to provide further information. Further information can be obtained by calling the number above.

Thank you.

## ***EXAMPLE Participant Consent Form***

I, the undersigned: ....., hereby agree to take part in the study '**Pilot Study of Remote Health Status Questionnaire Completion by Mobile Phone in Patients with Osteoarthritis**'.

The objectives and conditions of the study in which I agree to take part have been explained to me by Prof Nicholas Bellamy, Director of the Centre of National Research on Disability and Rehabilitation Medicine (CONROD) at the University of Queensland and Principal Investigator on this project.

I have read and understood the patient information document given to me. I have felt free to ask all the questions I needed to ask, and to take into account the answers given to me.

I understand that participation in the study will not result in any immediate or direct benefit to me, but that the information may inform the development of techniques of future value in the assessment of individuals with hip and knee osteoarthritis.

I have clearly understood that my participation in the study is voluntary and that I can withdraw my consent at any time, irrespective of my reasons, without incurring any liability and without my so doing influencing the quality of the healthcare given to me or my physician's attention.

Other than those people who will process the information under the strictest medical secrecy, my anonymity will be protected.

I do not relinquish any of my statutory rights by signing this document.

I agree to the data recorded during the study undergoing computerized processing by the principal investigator and research staff under his/her direct supervision. I understand that those research staff will be bound by the same conditions regarding confidentiality and my anonymity.

I have read, understood and agree to participate in the study entitled '**Pilot Study of Remote Health Status Questionnaire Completion by Mobile Phone in Patients with Osteoarthritis**'.

Signed .....

On...../...../.....

Witness.....

On...../...../.....