Research Participant Information Statement

"A double-blinded randomised controlled trial assessing the effect of oral ibuprofen on outcome of flexor tendon repairs"

Dr. Rahul Bamal, Dr. David James Graham, Professor Randy Bindra

(1) **What is the study about?**

You [i.e., the research participant] are invited to participate in a study of oral ibuprofen assessing its effect on outcome of hand flexor tendon repairs. We hope to learn whether oral ibuprofen affects outcome in patients after repair of hand flexor tendons. It is not definitely known whether oral ibuprofen alone will have an effect on the outcome of flexor tendon repairs but some prior studies have shown a positive effect of ibuprofen. You are selected as a possible participant in this study because you have flexor tendon injury and you also fulfill inclusion criteria. You also do not have any condition that excludes your participation in the study as per protocol.

If you decide to participate, we will explain all the procedures that are to be followed by you. There will be no change in the technique of your surgery or rehabilitation protocol if you choose to participate. When you choose to participate you will be given a participant number and will be randomised to either of the two arms of study.

Depending on your study arm, you will either receive oral ibuprofen 400 mg three times a day for three weeks or oral paracetamol 1000 mg three times a day for three weeks. Both drugs are painkillers and are also used in standard practice for pain relief. Both above medications (depending upon your study arm) will be provided by hospital in prepacked packets and will not incur any cost to you.

You will further be advised to take breakthrough pain medication that will be tablet oxycodone 10 mg 6 hourly per oral on an as-needed basis when you assess your pain as more than 4 on a scale of 0-10 with 10 being highest possible grade of pain. Breakthrough pain medication will not be supplied by the hospital as part of study. You will not know whether you are receiving ibuprofen or paracetamol as this is a blinded study. You will be assessed at 6 weeks and 12 weeks after surgery and those will be part of routine visits and not additional ones. You will be asked certain questions to assess your hand function and you will also be physically examined as is done routinely for other such type of patients. Study participation may take extra 15-20 minutes of your time per visit. Other regular follow up visits as per standard of care will occur including a clinical evaluation on

post-operative day 10 and appointments with hand therapy that start as early as a couple of days post surgery and take place every week or sooner during initial rehabilitation phase.

It should be clear that you will be randomly assigned to receive either the ibuprofen or paracetamol (i.e. there is only a chance that as a participant you will receive the drug being evaluated).

There is no expectation that the participation in the study will put any extra financial burden on you. By participating in this study there will not be any financial benefits to you but you might experience improved outcome if you are enrolled onto ibuprofen arm of the study and our hypothesis is proven true after the completion of study and data analysis. You may end up spending less on your routine pain medication (not breakthrough pain medication) as they are being provided by the hospital as part of study. There is no perceived risk of significant side effects as all individuals having conditions that predispose them to side effects or have any contraindications to either drug will not be included in the study. You may encounter mild side effects like nausea, indigestion, itching and so on.

Possible side effects of ibuprofen that are rare but you should be attentive for include:

- Dark urine, clay coloured stools, yellowing of skin and whites of eyes.
- Drooping of face, limb weakness or paralysis, chest pain, unconsciousness
- Vomiting blood, blood in urine or black stools

Possible side effects of paracetamol that are rare but you should be attentive for include:

- Dark urine, clay coloured stools, yellowing of skin and whites of eyes

You are encouraged to contact the research team should you experience any side effects or in rare case of pain being not under control even after taking prescribed medications. You should also not take any painkillers that are not prescribed while you are on trial medications. You can also contact orthopaedics outpatient clinic during office hours or emergency department, out of office hours and be directed to orthopaedic registrar on call. We have an option of taking you off the study due to side effects if required, that is discontinuing the study medications.

It is very important for you as a participant to be as diligent as possible in following the directions with regards to research intervention in order to help us derive accurate information from this study. Your non compliance can result in compromising study outcome and may also increase the frequency of adverse effects.

Contact persons: Professor Randy Bindra, Chief Investigator, Ph: 0756870334, E Mail: Randipsingh.Bindra@health.qld.gov.au

Ms. Holly Campbell, A/Academic Officer, Ph: 0756870334, Email: GCUHOrthoAcademics@health.qld.gov.au

A6, Clinical Administration, Department of Orthopaedics, Gold Coast University Hospital, 1 Hospital Boulevard, Southport, QLD 4215

(2) **Who is carrying out the study?**

The research is being conducted by Professor Randy Bindra, Department of Orthopaedic Surgery, Gold Coast University Hospital and co-investigators.

(3) **What does the study involve?**

As a participant in this study, you will be involved in taking the provided medications timely, attending scheduled clinic visits, undergoing clinical examination and answering questions for assessment of your hand function during your visits to clinic.

(4) **How much time will the study take?**

Each participant is required to dedicate approximately 15-20 minutes extra during each visit to clinic (two of them) for the purpose of study.

(5) **Will I incur any costs by participating in the study?**

You will not incur any costs by participating in the study. On the contrary you may end up spending less on your routine pain medication (not breakthrough pain medication) as they are being provided by the hospital as part of study.

(6) **Can I tell other people about the study?**

Yes you can tell other people about the study.

(7) **Will I receive the results of the study?**

You will be provided the research findings after publication of data upon request by email to GCUHOrthoAcademics@health.qld.gov.au.

(8) **Confidentiality and disclosure of information**

Any information that is obtained in connection with this study able to be identified as in connection with you will remain confidential and will be disclosed only with your permission, except as required by law. If you consent to participating in this study, we plan to present the findings at scientific meetings and publish the results in journal of repute but no information that can lead to your identification will be disclosed.

(9) **Can I withdraw from the study?**

Participation in this study is voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw at any stage without affecting your relationship with the Gold Coast Hospital & Health Service. You can withdraw your consent by advising the researcher either verbally, via email, or by completing and returning the 'Participant Withdrawal of Consent Form' that is supplied herein.

(10) **How can I obtain further information?**

When you have read this information, researcher will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact either the researcher or Ms Holly Campbell, A/Academic Affairs Officer, 0756870334, GCUHOrthoAcademics@health.qld.gov.au

(11) **What can I do if I have a complaint or a concern?**

Any concerns or complaints about the conduct of this study should be directed to the:

HREC Secretary
Gold Coast University Hospital
1 Hospital Boulevard
SOUTHPORT QLD 4215
Email: GCHEthics@health.qld.gov.au

Any complaint will be investigated promptly and you will be informed of the outcome.

This information sheet is for you to keep.

Research Participant Consent Form

Research Study Title "A double-blinded randomised control trial assessing the effect of oral ibuprofen on outcome of flexor tendon repairs"

Researcher's Name Dr. Rahul Bamal, Dr. David James Graham, Professor Randy Bindra

Participant Consent

I _____, agree to participate in this research. I have read the Research Participant Information Statement and had any question I have about the research answered for me by the researcher.

Please complete, placing a in applicable boxes

_____
Name of Research Participant *(First name and Surname)(Print)*

Are you 18 years of age or older? Yes
 No - A parental consent form is required to be completed.

_____ _____
Research Participant Signature Date

_____ _____
Name of Witness Relationship of Witness to Research Participant *(e.g., friend, sibling, parent, partner)*

_____ _____
Witness Signature Date

_____ _____
Researcher's Signature Date

Gold Coast Health
Building a healthier community

Research Participant
Withdrawal of Consent Form

You can withdraw your participation consent by advising the researcher verbally, via email to [*GCUHOrthoAcademics@health.qld.gov.au]* or by returning this completed form to [*Clinical Administration, Block A, Level 6, Gold Coast University Hospital, Southport, QLD 4215*].

Research Study Title "A double-blind randomised controlled trial assessing the effect of oral ibuprofen on outcome of flexor tendon repairs"

Researcher's Name Dr. Rahul Bamal, Dr. David James Graham, Professor Randy Bindra

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Gold Coast Hospital and Health Service.

Research Participant Name *(Print)*

_____ _____

Research Participant Signature Date