

24 January 2018

Enquiries to: HREC Coordinator
Phone: 07 5687 3879
HREC Ref: HREC/17/QGC/322
E-mail: GCHEthics@health.qld.gov.au

Professor Randy Bindra
Gold Coast University Hospital
1 Hospital Boulevard
Southport QLD 4215

Dear Professor Bindra

HREC Reference: HREC/17/QGC/322
Project title: A double blind randomised controlled trial assessing the effect of oral ibuprofen on outcome of flexor tendon repairs

Thank you for submitting the above project for ethical and scientific review, which has been undertaken by the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC).

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2015*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with speciality and affiliation with the Hospital and Health Service (HHS) (Attachment I).

This research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2015*.

HREC approval is valid for **3 years**. Expiry 24 January 2021

The documents reviewed and approved include:

Document	Version	Date
Application (AU/1/D62235)		14 November 2017
Protocol	4	23 January 2018
Participant Information Sheet and Consent form	4	23 January 2018
CP18-Tendon-Outcome-Assessments		
CV Prof Randy Bindra		June 2017
CV Dr. Rahul Bamal		29 September 2017
CV Dr David Graham		2017
Flexor Tendon Repair: Early Active Motion (EAM)		
Product_description_Ibuprofen		
Product_Description_Paracetamol		

Please note the following conditions of approval:

1. **This letter constitutes ethical approval only.** A copy of this approval must be submitted to the HHS Research Governance Officer/(RGO) along with a completed Site Specific Assessment (SSA) Form and applicable documents for authorisation from the CE to conduct this research within the HHS
 - a. Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the office of the Human Research Ethics Committee GCHEthics@health.qld.gov.au
2. **Reporting to the HREC:** The following reports are required to be submitted to the HREC. Failure to fulfill these reporting requirements may result in withdrawal or suspension of HREC approval:
 - a. **Progress Reports:** The Coordinating/Principal Investigator will provide a progress report annually to the HREC and at completion of the project. Progress reports are due on the anniversary of the HREC approval date.
 - b. **Safety Reporting:** The Coordinating/Principal Investigator will immediately report, in the specified format, anything which might warrant review of ethical approval of the project, including:
 - i. **Serious Adverse Events which impact on the ethical or scientific validity of the project must be notified to the HREC as soon as possible.** In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.
 - ii. If required, the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form.
 - iii. Unforeseen events that might affect continued ethical acceptability of the project.
 - c. **Other monitoring:** The HHS administration and/or the HREC may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on HHS premises or claiming any association with the HHS; or which the Committee has approved if conducted outside its HHS.
3. **Amendments to this project:**
 - a. **Amendments for review by an HREC:**
 - a. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review.
 - b. Amendments should be reflected in a cover letter from the Principal Investigator, providing a brief description and rationale for the changes, and their implications for the ongoing conduct of the study. All relevant updated documentation should also be provided. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf
 - b. **Amendments for review by an RGO:**
 - c. Amendments to the research project which affect only the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).
 - c. **Amendments for review by an HREC Coordinator:**
 - d. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC Coordinator. These should include a cover letter from the Principal Investigator providing

a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

4. **Early termination or routine completion of the project:**
- a. The HREC must be notified if the project is discontinued at a site before the expected date of completion. Notification should be in the form of a cover letter from the Principal Investigator, providing a rationale for the early termination.
 - b. For projects that are completed, the HREC must be notified by submission of a progress report, along with a copy of any research summaries or intended publications.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on ph. 07 5687 3879. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

The HREC wishes you every success in your research.

Yours sincerely



Carine Hoyer
HREC Coordinator
On behalf of
Emeritus Professor Drew Nesdale
Chair
Gold Coast Hospital and Health Service
Human Research Ethics Committee (EC00160)

Sites Approved

Site	Principal Investigator/s
Gold Coast Hospital and Health Service	Prof Randy Bindra; Dr Rahul Bamal; Dr David James Graham;