

HREC/14/QTHS/75_3
Human Research Ethics Committee
Townsville Hospital and Health Service
07 4433 1440



Townsville
Hospital and Health Service

2nd June 2014

Dr Marlow Coates
PO Box 6662
MACKAY MC QLD 4741

Dear Dr Coates

HREC reference number: HREC/14/QTHS/75

Project title: Correlation between HbA1c and Length of Hospital Stay in Total Hip and Knee Replacements: A Prospective Observational Cohort Study

Thank you for submitting the above project for ethical and scientific review. This project was considered out of session by Townsville Hospital and Health Service Human Research Ethics Committee (HREC) Chairperson on 19th May 2014.

The Townsville Hospital and Health Service HREC is constituted and operates in accordance with the National Health and Medical Research Council's "*National Statement on Ethical Conduct in Human Research (2007)*", *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)*, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)* and the "*CPMP/ICH Note for Guidance on Good Clinical Practice*". Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment 1).

The Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved include:

Document	Version	Date
Covering Letter	1.0	19/03/2014
Application	1.0	21/03/2014
Study Protocol	1.0	21/03/2014
Master Letter of Invitation	1.0	21/03/2014
Master Participant Consent Form	1.0	21/03/2014
Master GP Letter Template	1.0	21/03/2014
Private Practice Trust Fund Application		
Peer Review	1.1	24/04/2014
Curriculum Vitae – Dr Marlow Coates		
Curriculum Vitae – Dr Daniel Bartlett		
Curriculum Vitae – Alison Pighills		

The research project has ethical approval for the following sites:
Mackay Base Hospital

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Health Service CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at the approved Hospital and Health Service.

Please note the following conditions of approval:

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

Unforeseen events that might affect continued ethical acceptability of the project.

Serious Adverse Events must be notified to the Committee as soon as possible. In addition 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. 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.

Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online application form (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised application form, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Amendments to the research project which only affect 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).

Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, then submitted to the RGO.

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.

The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

The Health Service administration and the Human Research Ethics Committee 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 hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside the approved Hospital and Health Service.

HREC approval is valid until the 31 December 2015

Should you have any queries about the HREC's consideration of your project please contact me on (07) 4433 1440. 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

Once site specific 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.

The HREC wishes you every success in your research.

Yours sincerely



A/Prof Andrew Crowden
Chairperson
Townsville Hospital and Health Service
Human Research Ethics Committee

Townsville Hospital and Health Service
Human Research Ethics Committee
Telephone +617 4433 1440
Email TSV-Ethics-Committee@health.qld.gov.au