



Townsville
Hospital and Health Service

27th June 2016

Dr Daniel Bartlett
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Mackay Base Hospital

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Dear Dr Bartlett,

HREC reference number: HREC/16/QTHS/98

Project title: The impact of endoscopy sedation information sheets on the level of concern regarding possible awareness in patients undergoing endoscopy sedation

Thank you for providing a response to the Committee's concerns regarding the above project. The correspondence was considered by members and the Chair of the Townsville Hospital and Health Service Human Research Ethics Committee (HREC) on 23/06/2016.

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007). The Townsville Hospital and Health Service HREC operates in accordance with the '*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*' (NHMRC, 2003); and the '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007). Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

The Human Research Ethics Committee has granted approval of this research project. The research proposal meets the requirements of the '*National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)*'. The documents reviewed and approved include:

Document	Version	Date
Response letter		14.06.16
Study Protocol		14.06.16
Patient Information and Consent Form	2.0	14.06.16
NEAF (AU/1/6D46220)	2.0	22.05.16
Letter of support – Dr Dale Hanson		23.03.16
Grant approval - Mackay PPTF		13.11.15
Endoscopy Sedation Information Sheet - ASA	Ed 3	04.07.14
Consent Information – Qhealth	1.0	02/2008
Colonoscopy – procedural consent form	8.0	02/2011
Endoscopy – procedural consent form	8.0	02/2011
Pre-Procedure Survey	1.0	04.04.16
Post-Procedure Survey (Recovery)	1.0	04.04.16
Post-Procedure Survey (Discharge)	1.0	04.04.16
Curriculum Vitae – A.Pighills		10.11.15
Curriculum Vitae – L.Gan Lim		11.11.15
Curriculum Vitae – Z. Tong		10.11.15

The research project has ethical approval for the following sites:
Mackay Hospital and Health Service

Please note the following key dates for this study:

HREC approval expiry: 26/06/2021

Annual report due: 26/06/2017

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 and supporting study documents for authorisation from the CEO or Delegate to conduct this research at the approved sites. Refer to the local THHS website for further information on Site Specific Assessment: <http://qheps.health.qld.gov.au/tville/district-executive/medical-services/mssu-ethics.htm>

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: please notify the HREC if any occur 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 final report should include a copy of the results and/or publication, if not available at the time of reporting these must be provided in a timely manner.

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 sites.

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.

Kind regards



**Ms Mary Leech
Deputy Chairperson
Townsville Hospital and Health Service
Human Research Ethics Committee**