Research Education Support & Administration Unit
Phone: +617 4433 1351
File Number: SSA/17/QTHS/149
Our Reference: dbs/ TRESA/RGO/2017/149_1

Queensland Government

Townsville
Hospital and Health Service

Dr Chris Butler
Consultant
Townsville Hospital and Health Service

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Dear Dr Butler

HREC Reference Number: HREC/17/QTHS/102
SSA Reference Number: SSA/17/QTHS/149
Project Title: Effect of intraoperative magnesium on the incidence of chronic post surgical pain after thoracotomy

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that Townsville Hospital and Health Service authorisation has been granted for this study to take place at the following site(s):

Townsville Hospital and Health Service

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. Townsville Hospital and Health Service governance authorisation is valid until **17 July 2022**. The study cannot continue after this date unless governance authorisation has been given to do so. If you require an extension to this date you must send in a written request to us with a rationale for the extension request.

2. Continuation of governance authorisation is subject to and conditional upon the receipt of annual reports and continuation of ethical approval of this study. In the event that ethical approval for this study lapses or otherwise comes to an end, then governance authorisation will also cease.

3. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project are to be submitted to the HREC for review. A copy of the HREC approval letter and the relevant documentation must be submitted to the Research Governance Officer (RGO).

4. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the RGO.

5. A proposed amendment to the research protocol or conduct of the research which may affect both the going ethical acceptability of the project and the site acceptability of the project are to be submitted firstly to the HREC for review and then to the RGO after HREC approval has been granted.

6. The Principal Investigator must keep detailed records of all reported adverse events and maintain up-to-date tabulations and/or line listings.

7. As Townsville Hospital and Health Service is the study sponsor the Principal Investigator will immediately report anything to the THHS RGO which might warrant review of authorisation of the project, including:
   a) Within 24 hours of becoming aware of the event:
      a) all serious adverse events (SAEs), except those that are identified in the protocol as not needing immediate reporting;

b) all significant safety issues;
c) all urgent safety measures (USM) taken as a response to the significant safety issue;
d) all Suspected Unexpected Serious Adverse Reactions (SUSARs);
e) any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner).

b) As specified in the protocol:
a) all safety critical events;
b) any additional requested information relating to reported deaths.

8. The Principal Investigator must notify the approving HREC of the following:
a) Within 72 hours of becoming aware of the event:
a) All significant safety issues that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial;
b) Urgent Safety Measures (USMs) in response to a significant safety issue.
b) Within 15 calendar days of becoming aware of the event:
a) All other significant safety issues;
b) Notification of temporary halt of a trial for safety reasons;
c) Early termination of a trial for safety reasons.

9. For clinical trials conducted under the CTN / CTX scheme, the Principal Investigator must notify the Therapeutic Goods Administration (TGA) of the following:
a) Within 24 hours of becoming aware of the event:
a) Urgent Safety Measures (USMs) in response to significant safety issue;
b) all suspected unexpected serious adverse reactions (SUSARs) occurring in Australian participants.
b) Within 72 hours of becoming aware of the event:
a) All significant safety issues that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial and require an urgent safety measure.
c) Immediately, but no later than 7 calendar days after being made aware of the event:
a) All fatal or life threatening Australian SUSARs, with any follow-up information within a further 8 calendar days.
d) Within 15 calendar days of becoming aware of the event:
a) All other significant safety issues;
b) All other Australian SUSARs;
c) Notification of temporary halt of a trial for safety reasons;
d) Early termination of a trial for safety reasons.

10. Where applicable, all industry safety monitoring and or Data and Safety Monitoring Board (DSMB) reports must be submitted to the RGO. Do not submit individual line listings when submitting an industry or DSMB report.

11. The Principal Investigator will provide an annual report to the RGO 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. For clinical trials the annual report must include a safety report including a clear summary of the evolving safety profile of the trial.

12. THHS must be acknowledged as an affiliation in any presentations and or publications arising as a result of the study.

The Site Specific documents received and considered approved with this are:

Documents	Version	Date
THHS Consent to Participate (based on Master Consent to Participate version 2.0 dated 08.07.2017)	1	21.08.2017

We also note the following for our records:

Documents	Version	Date
Study Protocol	2.0	08.07.2017
Consent to Participate	2.0	08.07.2017
Clinician Information Sheet	1.0	03.09.2017
Emergency Contact Card	1.0	03.09.2017
Safety Monitoring Plan signed by Dr Claire Furyk		06.10.2017
Confirmation of CTN Notification		05.10.2017
Email of Support – Kelvin Robertson		29.12.2017
Email of Support – NUM Perioperative		03.01.2018
Ethics Application – AU/1/DE1E29		24.05.2017
Curriculum Vitae – Antimony Mar		
Curriculum Vitae – Akhilesh Tiwar		
HREC Approval Letter		18.07.2017
HREC Amendment Approval Letter		21.09.2017

On commencement of your research protocol can you please complete and forward the attached Notification of Commencement form to the RGO administrator.

Should you require any additional information, please do not hesitate to contact me on (07) 4433 1351.

Yours sincerely

Sue Jenkins-Marsh
Research Governance Officer
Townsville Hospital and Health Service
18 /01 /2018

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Queensland Government

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NOTIFICATION OF COMMENCEMENT OF RESEARCH

SSA Reference number: SSA/17/QTHS/149

HREC Reference number: HREC/17/QTHS/102

Project Title: Effect of intraoperative magnesium on the incidence of chronic post surgical pain after thoracotomy

Principal Investigator: Dr Chris Butler

The above research commenced on: / /

Signature: _____ **Date:** / /
Principal Investigator

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