

11 December 2014

Mr Mulford
[ADDRESS]

Sent via email

Dear Mr Mulford

REF NO: H0014512
TITLE: Dexamethasone to reduce pain, nausea and vomiting, improve mobilisation and reduce hospital stay in hip and knee arthroplasty: a double blind controlled trial

Document	Version	Date
Data collection		22 Oct 2014
Dexamethasone consumer information		
Dexamethasone product information	version 5.0	
LGH Consent Form	version 1	
NEAF Application		
Patient Information	version 1	
Preadmission Screening	version 1	1 Sept 2014
Readiness for discharge		
Study Protocol	version 2	20 Oct 2014

The Tasmanian Health and Medical Human Research Ethics Committee considered and approved the above documentation on **09 December 2014** to be conducted at the following site(s):

Launceston General Hospital

Please ensure that all investigators involved with this project have cited the approved versions of the documents listed within this letter and use only these versions in conducting this research project.

This approval constitutes ethical clearance by the Health and Medical HREC. The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approvals of other bodies or authorities are required. It is recommended that the

proposed research should not commence until you have satisfied these requirements.

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the *National Statement on the Ethical Conduct in Human Research* (NHMRC 2007 updated 2014).

Therefore, the Chief Investigator's responsibility is to ensure that:

- (1) The individual researcher's protocol complies with the HREC approved protocol.
- (2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC. Please note that all requests for changes to approved documents must include a version number and date when submitted for review by the HREC.
- (3) Section 5.5.3 of the National Statement states:

Researchers have a significant responsibility in monitoring approved research as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies and take prompt steps to deal with any unexpected risks.

The appropriate forms for reporting such events in relation to clinical and non-clinical trials and innovations can be located at the website below. All adverse events must be reported regardless of whether or not the event, in your opinion, is a direct effect of the therapeutic goods being tested.

http://www.research.utas.edu.au/human_ethics/medical_forms.htm

- (4) All research participants must be provided with the current Patient Information Sheet and Consent Form, unless otherwise approved by the Committee.
- (5) The Committee is notified if any investigators are added to, or cease involvement with, the project.
- (6) This study has approval for 4 years contingent upon annual review. A *Progress Report* is to be provided on the anniversary date of your approval. Your first report is due 9 December 2014. You will be sent a courtesy reminder closer to this due date.
- (7) A *Final Report* and a copy of the published material, either in full or abstract, must be provided at the end of the project.

Should you have any queries please do not hesitate to contact me on (03) 6226 6254.

Yours sincerely

Jude Vienna-Hallam

Digitally signed by Jude Vienna-Hallam
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