Queensland Health

Office of the Human Research Ethics Committee

Queensland Government

21 October 2014

Enquiries to: Tanya Douglass
Phone: (07) 5687 3879
Our Ref: HREC/14/QGC/151
E-mail GCHEthics@health.qld.gov.au

Dr Alex Mowat
C/O Department Urogynaecology
Gold Coast University hospital
SOUTHPORT QLD 4215

Dear Dr Mowat,

HREC Reference number: HREC/14/QGC/151
Project title: Infusion method vs. standard auto-fill trial of void protocol following a TVT-exact procedure: a randomized control trial

Thank you for submitting the above project for ethical and scientific review. This project was first considered by the Gold Coast Health Service District Human Research Ethics Committee (HREC) held on 21 October 2014.

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), 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 specialty and affiliation with the Hospital (Attachment I).
I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved include:

Document	*Version*	*Date*
Covering Letter: Cover letter introducing trial	1	13 August 2014
Application		
Protocol: Study protocol	1	12 August 2014
Patient Information Sheet/Consent Form: patient brochure and consent form	1	12 August 2014
Trial of void protocol lReferred to a Figure 1 in the protocol.	1	12 August 2014
Investigator CV: Alex Mowat CV	1	13 June 2014
Response to Request for Further Information		23 September 2014

Please note the following conditions of approval:

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

2. 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 NEAF (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 NEAF, 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

3. 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).

4. 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.

5. 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.

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

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

8. The District 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 Gold Coast Hospital Health Service.

HREC approval is valid for **three (3) years** from the date of this letter. **Expiry 21 October 2017.**

Should you have any queries about the HREC's consideration of your project please contact Emer./Prof Drew Nesdale via (07) 5687 3879 or GCHEthics@health.qld.gov.au. 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

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 District CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the District 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 Gold Cost Hospital and Health Service.

Once authorisation to conduct the research has been granted, please complete the Commencement Form and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours faithfully

for
Emer/Prof. Drew Nesdale
CHAIR
HUMAN RESEARCH ETHICS COMMITTEE
GOLD COAST HOSPITAL AND HEALTH SERVICE