Enquiries to: Deborah Wainwright
Telephone: (61 7) 4616 6696
Our Ref: LNR/2020/QTDD/60280

Queensland Government

Allied Health Services

Darling Downs Hospital and Health Service

Dr Devang Desai
Specialist Urologist
Toowoomba Hospital

Dear Dr Desai

HREC Reference number: LNR/2020/QTDD/60280
Project title: Evaluating Donor Site Complications after Buccal Mucosal Grafting for Urethroplasty.

Thank you for submitting the above project for ethical and scientific review. This project was considered by the Darling Downs Health Human Research Ethics Committee (HREC).

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 (updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project at the following sites:

- Toowoomba Hospital
- St Vincent's Private Hospital Toowoomba

Please note: **This letter constitutes ethical approval only**. A copy of this approval must be submitted to the HHS Research Governance Officer (RGO) along with a completed Site Specific Assessment (SSA) Application and applicable documents for authorisation from the CE or delegate to conduct this research within the HHS.

The documents reviewed and approved include:

Document	*Version*	*Date*
LNR application		13 February 2020
Protocol	V 3	March 2020
CV – D Desai		
CV – M Ong		
CV – H Flynn		

Please note the following conditions of approval:

1. **Your request for a Waiver of Consent is granted.**
   Please consider the permissions under the Hospital and Health Boards Act 2011 or Public Health Act 2005 to enable access to confidential information for the purposes of research without consent. You may require a Public Health Act Approval (PHA).

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2. 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.
    b. 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.

3. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted via Ethical Review Manager to the HREC for review. 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 RGO via Ethical Review Manager (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 to 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 via Ethical Review Manager 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.

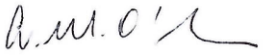
7. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

8. The District administration and the HREC 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 Darling Downs Health.

HREC approval is valid for 3 years from the date of this letter.
Should you have any queries about the HREC's consideration of your project please contact the Chair of the Darling Downs Health Human Resource Ethics Committee. 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

The HREC wishes you every success in your research.

Yours sincerely



Angela O'Shea
Chair
Human Research Ethics Committee
Darling Downs Health

18 / 03 / 2020