

11/06/2019

Dear Professor David Gillatt,

**Reference No: 5201937998816**

**Title:** 3799 - *Novoglan-01 clinical trial to confirm safety, efficacy and tolerability of the Novoglan product in treating adult phimosis*

Thank you for submitting the above application for ethical and scientific review. Macquarie University Human Research Ethics Committee HREC Medical Sciences Committee considered your application.

I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted by Professor David Gillatt and other personnel: MS Tiffany Mackay.

**Approval Date:** 30 June 2019

This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research* (2007, updated July 2018) (the *National Statement*).

**Standard Conditions of Approval:**

1. Continuing compliance with the requirements of the *National Statement*, which is available at the following website:  
<http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>
2. This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.
3. All adverse events, including events which might affect the continued ethical and scientific acceptability of the project, must be reported to the HREC within 72 hours.
4. Proposed changes to the protocol and associated documents must be submitted to the Committee for approval before implementation.

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact the Ethics Secretariat on 9850 4194 or by email [ethics.secretariat@mq.edu.au](mailto:ethics.secretariat@mq.edu.au)

The HREC Medical Sciences Committee Terms of Reference and Standard Operating Procedures are available from the Research Office website at:  
<https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics>

The HREC Medical Sciences Committee wishes you every success in your research.

Yours sincerely,



Professor Anthony Eyers  
Chair, HREC Medical Sciences Committee

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 July 2018) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*

**Details of this approval are as follows:**

**Approval Date:** 30 May 2019

The following documentation has been reviewed and approved by the HREC (Medical Sciences):

- Response to HREC queries 14-Mar-2019
- Macquarie HREA V1 11-Feb-2019
- Macquarie Clinical Research Executive Governance Endorsement
- Novoglan-01 Recruitment Plan V2.0 15-Mar-2019 (Clean & Tracked Changes)
- Novoglan-01 Protocol Summary V1.0 31-Oct-2018
- Novoglan-01 Clinical Trial Protocol V2.0 15-Mar-2019 (Clean & Tracked Changes)
- Novoglan-01 PICF V2.0 15-Mar-2019 (Clean & Tracked Changes)
- Novoglan-01 Participant Withdrawal Form V1 30-Oct-2018
- Novoglan-01 Phimosis Measurement Form V1.0 30-Oct-2018
- Novoglan-01 Quality of Life Questionnaire V1.0 30-Oct-2018
- Novoglan-01 Treatment Tolerability Questionnaire V1 30-Oct-2018
- Novoglan-01 Investigator Brochures V2.0 15-Mar-2019 (Clean & Tracked Changes)
- Novoglan-01 Illustrated User Guide 12-Oct-2018
- Novoglan-01 Safety Plan V1.0 12-Oct-2018
- Novoglan-01 Statistical Plan V1.0 28-Oct-2018
- Novoglan-01 Clinical Data Management Plan V1.0 12-Oct-2018
- Novoglan-01 Clinical Team Declaration of Publication Results
- Novoglan-01 CRF Final Study Visit V1.0 30-Oct-2018
- Novoglan-01 CRF Study Visit 1 V1.0 30-Oct-2018
- Novoglan-01 CRF Study Visit 2 V1.0 30-Oct-2018
- Novoglan-01 CRF Study Visit 3 V1.0 30-Oct-2018

Documents Noted:

- CV Prof David Gillatt 2018
- CV Bernard Riley 2018
- CV Tiffany Mackay 2018
- Novoglan-01 Financial Disclosure – Prof Gillatt
- Novoglan-01 Financial Disclosure – Bernard Riley
- Novoglan-01 Financial Disclosure – Tiffany Mackay
- Novoglan-Insurance-IPH001-Parent Company Confirmation Insurance Cover Nov-2018