

**Human Research Ethics Committee - Scientific and Ethical Review
Ethical Approval – Granted**

15 September 2015

Dear Dr Daniel van Langenberg

LR 61/2015 Evaluation of clinical outcomes in patients receiving immunomodulator therapy for inflammatory bowel disease at Eastern Health.

Principal Investigator: Dr Daniel van Langenberg
Associate Investigators: Dr Nina Parthasarathy, Dr Bei Ye and Ms Alicia Moltzen
Eastern Health Sites: BHH and MHH

Approval Period: On-going - subject to a satisfactory progress report being submitted annually

Thank you for the submission of the above project for review. The project has been reviewed by the Eastern Health Human Research Ethics Committee. The project considered negligible risk in accordance with definitions given in the National Statement (2007). All queries have now been addressed and the project is accordingly **APPROVED**.

Documents submitted for review:

- Low Risk & Negligible Risk Research Application Form version 2 dated 09 September 2015
- Cvs for Ms Alicia Moltzen and Dr Nina Parthasarathy
- Ms Alicia Moltzen signed Confidential form

Reporting Requirements:

Please note, an **annual progress report is required every February for the preceding calendar year until project completion**. Continuing approval is subject to the timely submission of a satisfactory progress report. Progress report template can be downloaded from our web-page:

<http://www.easternhealth.org.au/research-ethics/research-ethics/quick-links-to-forms-and-templates>

Please ensure you notify the Ethics Committee of all personnel changes and any serious adverse events that may affect study conduct. Any changes to the approved Protocol or other approved documents must be submitted for ethical review and approval prior to use.

Please quote our reference number **LR61/2015** in all future correspondence.

Yours sincerely



Jacob Achuoth
Research Ethics and Governance Officer
Office of Research and Ethics

On behalf of:

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director Medical Services and Research (Site Authorisation)

Copy to: Dr Nina Parthasarathy, Dr Bei Ye and Ms Alicia Moltzen

Confidentiality, Privacy & Research

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices.

Electronic storage devices must be password protected or encrypted.

The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications

Whilst the Eastern Health Research and Ethics Committee is an independent committee, the committee and Eastern Health management encourage the publication of the results of research in a discipline appropriate manner. Publications provide evidence of the contribution that participants, researchers and funding sources make.

It is very important that the role of Eastern Health is acknowledged in publications.