

**Contact:** Sydney Local Health District Human Research Ethics Committee –  
CRGH  
Concord Repatriation General Hospital (CRGH)  
Concord NSW 2139  
Telephone: (02) 9767 5622  
Email: [crgh.ethics@sswahs.nsw.gov.au](mailto:crgh.ethics@sswahs.nsw.gov.au)



CONCORD  
REPATRIATION GENERAL  
HOSPITAL

26 May 2017

A/Professor Rupert Leong  
c/- Dr Webber Chan  
Gastroenterology Department  
CONCORD RGH

Dear Professor Leong,

**Re: HREC/17/CRGH/22 CH62/6/2017-015  
Vedolizumab Immunomodulator Enforced Withdrawal Study (VIEWS)**

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 23 February 2017. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and final ethical approval has been granted.

The documents reviewed and approved include:

|   | IDENTIFICATION NUMBER          | DATE       |
|---|--------------------------------|------------|
| National Ethics Application Form (NEAF)             | Submission code<br>AU/1/745B28 | 23/01/2017 |
| Protocol  | Version 3                      | 26/05/2017 |
| Master Participant Information Sheet & Consent Form | Version 2                      | 13/03/2017 |
| Data Collection Form                                | Version 2                      | 13/03/2017 |
| Study ID log  | Version 1                      | 21/02/2017 |

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital

*You are reminded that this letter constitutes ethical approval only. You must not commence this research project at Concord Hospital until a Site Specific Application has been reviewed and approved and separate authorisation from the Chief Executive or delegate has been obtained*

2. Bankstown Hospital
3. Blacktown Hospital
4. Royal Prince Alfred Hospital

*Please forward a copy of this letter to all site investigators for submission to the relevant Research Governance Officer*

Please note the following conditions of approval:

1. You will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project, (including Serious Adverse Events).
2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.
3. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. You will provide an annual report to the HREC, and at completion of the study in the specified format.
5. You will adhere to the study protocol at all times.
6. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.
7. Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.
8. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the Concord Hospital Research Office by **31/05/2018**.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: [www.sswahs.nsw.gov.au/concord/ethics](http://www.sswahs.nsw.gov.au/concord/ethics) .

We wish you every success in your research.

***Please quote the above file number in all correspondence.***

Yours sincerely,



**Professor Andrew McLachlan**  
Chairman


**Sydney Local Health District Human Research Ethics Committee – CRGH**

**Please complete the boxes below and return a copy of this page to the Concord Hospital Research Office:**

I acknowledge and accept the Conditions of Ethical Approval.

I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained

R. LEONG.  
Printed Name  
Chief Investigator

  
Signature

20 Jun 2017  
Date