

Contact: Sydney Local Health District Human Research Ethics Committee
Concord Repatriation General Hospital
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: CH62/6/2021-055



CONCORD
REPATRIATION GENERAL
HOSPITAL

02 June 2021

Professor Rupert Leong
Dr Aviv Pudipeddi
Gastroenterology Department
Concord Repatriation General Hospital

Dear Prof Leong,

Re: Local reference number: CH62/6/2021-055
REGIS ethics application number: 2021/ETH00712
REGIS project ID number: 2021/PID00882
Project title: Knowledge and attitudes towards the use of histology in inflammatory bowel disease

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Executive Ethical Review Panel of the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 22 April 2021. 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 final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*.

The documents reviewed and approved include:

	VERSION	DATE
Human Research Ethics Application (HREA)	3	01 June 2021
Protocol	2	17 May 2021
Participant Information Sheet & Consent Form	2	17 May 2021
Research Data Management Plan	2	17 May 2021
Survey	2	17 May 2021
Support letter	N/A	11 May 2021
Template email	No version	No date

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 any site until you have submitted a Site Specific Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. 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 HREC by **02/06/2022**. You must also provide an annual report to the HREC upon completion of the study.
2. You will adhere to the study protocol at all times.
3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.
4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).
6. It is noted that REDCap will be used for secure research data collection, management and storage in the study. Once the REDCap project has been set-up, using the SLHD Master Code Sheet Project, please provide a copy of the REDCap Project Codesheets with a version number and date to the Ethics Committee for review and approval prior to study commencement. Please note, the SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via [email](#) or [online](#) for consultation if necessary.

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: <https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html>

We wish you every success in your research.

Please quote the local reference number at the top of this letter in all correspondence.

Yours sincerely,



Professor David Le Couteur

Chair

Sydney Local Health District Human Research Ethics Committee – CRGH