



HUMAN RESEARCH ETHICS COMMITTEE

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05 March 2019 (updated 6 March 2019)

Professor Georgina Hold
Level 2, WR Pitney Building
St George Hospital
Short Street
KOGARAH NSW 2052

Dear Prof Hold

HREC ref no: 18/173 (HREC/18/POWH/357)

Project title: Defining the Australian Inflammatory Bowel Disease Microbiome- the AIM Study

Thank you for submitting the above application for ethical and scientific review and for your correspondence dated **1 March 2019** to the Executive Officer responding to questions which arose at the Executive Committee meeting on **22 February 2019**. Authority to grant final approval was delegated to the Executive Officer. I am pleased to advise that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research and ethics approval has been given for the following:

- HREA submission AU/1/B6F7315 dated 18 July 2018
- Protocol V1.5 dated 31 January 2019
- Master Adult Control PISCF V1.5 dated 31 January 2019
- Master Adult IBD PISCF V1.5 dated 31 January 2019
- AIM Child Control PISCF V1.5 dated 31 January 2019
- AIM Child IBD PISCF V1.5 dated 31 January 2019
- AIM Parent/Guardian Control PISCF V1.5 dated 31 January 2019
- AIM Parent/Guardian IBD PISCF V1.5 dated 31 January 2019
- AIM Young Child Control PIS V1 dated 22 November 2018
- AIM Young Child IBD V1 dated 22 November 2018
- Diet Diary V1.0 dated 1 March 2019
- Food Avoidance Questionnaire V1 dated 1 March 2019
- Partial Mayo Score dated 30 January 2019
- Paediatric Ulcerative Colitis Activity Index (PUCAI) dated 30 January 2019
- Crohn's Disease Activity Index (CDAI) dated 30 January 2019
- Paediatric Crohn's Disease Activity Index (PCDAI) dated 30 January 2019
- Simple Endoscopic Score for Crohn's disease dated 30 January 2019



**Prince of Wales Hospital &
Community Health Services**

Community Health Services
Barker Street
Randwick NSW 2031

- Crohn's Disease Patient Reported Outcome Measures (PRO III) dated 30 January 2019
- Rutgeert's Post-operative Endoscopic Index dated 30 January 2019
- Ulcerative Colitis Endoscopic Index of Severity (UCEIS) dated 30 January 2019
- Mayo Clinic Index: Endoscopic Subscore dated 30 January 2019
- Ulcerative Colitis PROM dated 30 January 2019
- Crohn's Disease Phenotype dated 30 January 2019
- Ulcerative Colitis Phenotype dated 30 January 2019
- SF-36 dated 30 January 2019
- AIM IBD-Q (children) V1 dated 9 July 2018
- AIM IBD-Q (Adult) V1 dated 9 July 2018
- AIM Study Schedule V1.5 dated 31 January 2019
- Dietary Questionnaire dated 30 January 2019
- Baseline Demographics (Adults) dated 30 January 2019
- Baseline Demographics (Children) dated 30 January 2019
- Impact-III dated 30 January 2019
- Food Intake Diary dated 30 January 2019
- Basic Demography Form dated 30 January 2019
- AIM Poster Healthy controls V1 dated 27 June 2018
- AIM Poster IBD V1 dated 17 June 2018

Ethics approval is valid for the following site(s):

- St George Hospital
- Prince Of Wales Hospital
- Concord Repatriation General Hospital
- Liverpool Hospital
- St Vincent's Hospital
- Sydney Children's Hospital Randwick
- Blacktown Hospital
- Canberra Hospital
- Royal Prince Alfred Hospital
- Wollongong Hospital
- Royal North Shore Hospital
- Westmead Children's Hospital

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.
4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.

5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For Public Health Sites: You are reminded that this letter constitutes ethics approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website:

<https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research>

Please quote **18/173** in all correspondence.

We wish you every success in your research.

Yours sincerely



Andrew Bohlken
Executive Officer, Human Research Ethics 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)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

