



Final Approval for Ethics Application

29 March 2019

Professor Paul Ward
College of Medicine and Public Health
Flinders Medical Centre

Dear Professor Ward,

OFR Number: 345.18

HREC reference number: HREC/19/SAC/39

Project title: What is the effect of a dietary resistant starch intervention on the colonic luminal environment and HIV-related immunity and is a feeding trial feasible in HIV-positive adults in India?

Chief Investigator: Professor Paul Ward

Ethics Approval Period: 29 March 2019 – 29 March 2022

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) (EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*.

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process.**

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

The below documents have been reviewed and approved:

Document	Version	Date
Human research ethics application	AU/1/4A4A312	15 March 2019
Protocol	4	15 March 2019
Participant information sheet and consent form	3	13 March 2019
Food frequency questionnaire (FFQ)	1	8 February 2019
Symptom tool	2	8 February 2019
Interview guide	1	29 January 2019
Literature review	1	29 January 2019

Terms and Conditions of Ethics Approval:

SALHN has recently introduced site monitoring of authorised studies. This approval/authorisation is subject to participation in this monitoring process. You will be notified in advance if your site has been selected for an inspection. It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. This ethical approval is subject to approval from Institutional Ethics Committee of the All India Institute of Medical Sciences.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* & the *Australian Code for the Responsible Conduct of Research (2018)*.
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely,



Professor Bill Heddle

Chair

Southern Adelaide Clinical Human Research Ethics Committee