Government of South Australia
SA Health

Central Adelaide Local Health Network
CALHN Human Research Ethics Committee
Level 3, Roma Mitchell House
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Adelaide, South Australia, 5000
Telephone: +61 8 7117 2229
Email: Health.CALHNResearchEthics@sa.gov.au

Approval Date: 03 May 2018

Professor Karen Jones
School of Medicine
UNIVERSITY OF ADELAIDE

Dear

Project Title: **Effects of a guar and whey containing preload (Omniblend) on the gastric emptying and blood pressure responses to oral glucose in healthy older subjects.**

HREC reference number: HREC/18/CALHN/197

CALHN Reference number: R20180318

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the Royal Adelaide Hospital Human Research Ethics Committee at its meeting held on 12 April 2018.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval. The study meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

Document	***Version***	***Date***
HREA Application	AU/1/AD15312	22 March 2018
Cover Letter	-	01 May 2018
Protocol	2	01 May 2018
Participant Information Sheet and Consent Form	2	01 May 2018
Radiation Report	-	09 March 2018
Advertising Flyer	1	09 March 2018

Sites covered by this approval:

- **Clinical Research Facility on level 4 of the University of Adelaide, Adelaide Health and Medical Sciences, SA** **CPI: Prof Paul Rolan**

HREC approval is valid for **5 years** from approval date **03 May 2018 to 03 May 2022.**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
- This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Clinical Trials. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.
- Adequate record-keeping is important and must be maintained in accordance with GCP, NHMRC and state and national guidelines. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- Researchers must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) adverse events which warrant protocol change or notification to research participants;
  (b) changes to the protocol;
  (c) changes to the safety or efficacy of the investigational product, device or method;
  (d) premature termination of the study.

- The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
- Confidentiality of the research participants shall be maintained at all times as required by law.
- Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
- **Annual review reports must be submitted to the HREC, every 12 months on the anniversary of the above approval date**. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the CALHN HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/
- The REC must be advised with a final report or in writing, and a copy of any published material, within 30 days of completion of the project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office: Health.CALHNResearchGovernance@sa.gov.au

This Committee is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact, Executive Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The HREC wishes you every success in your research.

Yours sincerely,

Ian Tindall
CHAIRMAN
CALHN HUMAN RESEARCH ETHICS COMMITTEE

cc: Site Research Governance Officer