Approval Date: 24 February 2016

HREC Reference number: HREC/16/RAH/34

CALHN Reference number: R20160218

Prof Karen Jones Discipline of Medicine University of Adelaide Central Adelaide Local Health Network
Royal Adelaide Hospital Human Research Ethics Committee
Level 4, Women's Health Centre

Royal Adelaide Hospital North Terrace

Adelaide, South Australia, 5000 Telephone: +61 8 8222 4139

Email: Health.CALHNResearchEthics@sa.gov.au

**Dear Prof Jones** 

Project Title: Effects of the artificial sweetener, sucralose, on blood pressure, heart rate and superior mesenteric artery blood flow compared to intraduodenal glucose infusion in healthy older subjects.

Thank you for submitting the above project for ethical review. This project was considered by the Chairman of the Royal Adelaide Hospital Human Research Ethics Committee. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates.* The documents reviewed and approved include:

- LNR Application: AU/1/1004212 Sites covered by this approval:
  - o Royal Adelaide Hospital: CPI Prof Karen Jones
- Protocol, Version 2, dated 24 February 2016
- Information Sheet and Consent Form, Version 1, dated 2, dated 24 February 2016

## GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- Adequate record-keeping is important. 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.
- You 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) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  - (b) changes to the protocol,
  - (c) premature termination of the study.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is valid for 5 years from the date of this letter, after which an extension must be applied for.
   Investigators are responsible for providing an annual review to the RAH REC Executive Officer each
   anniversary of the above approval date, within 10 workings days, using the Annual Review Form available
   at: <a href="http://www.rah.sa.gov.au/rec/index.php">http://www.rah.sa.gov.au/rec/index.php</a>
- The REC must be advised with a report or in writing within 30 days of completion.

Should you have any queries about the HREC's consideration of your project, please contact Ms Heather O'Dea on 08 8222 4139, or <a href="mailto:Health.CALHNResearchEthics@sa.gov.au">Health.CALHNResearchEthics@sa.gov.au</a>.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until governance authorisation from the Chief Executive or delegate of that site has been obtained.

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

The HREC wishes you every success in your research.

Yours sincerely,

A/Prof A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE