



Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service
Research Governance Office

Our Ref: 2014104EP

A/Professor Elizabeth Davis
Department of Endocrinology and Diabetes
Princess Margaret Hospital
Roberts Road
SUBIACO WA 6008

Dear A/Professor Davis

HREC REF **2014104EP**
STUDY TITLE **Dietary proteins contribution to the insulin dose required to maintain post-prandial euglycaemia.**

On behalf of the Child and Adolescent Health Service, I give authorisation for your research project to be conducted at the following site(s):

This authorisation is based on the approval from PMH HREC and the review from the Research Governance Office. This authorisation is valid subject to the ongoing approval from the HREC.

This authorisation is based on the ethical approval from the HREC, and on the basis of compliance with the 'Conditions of Authorisation to Conduct a Research Project at Site' (attached) and with the compliance of all reports as required by the Research Governance Office and approving HREC. Non compliance with these requirements could result in the authorisation being withdrawn.

The responsibility for the conduct of this project remains with you as the Principal Investigator at the site.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mark Salmon'.

Dr Mark Salmon
Executive Director
Medical Services

10/12/2014



Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service

Our Ref: 2014104EP

A/Professor Elizabeth Davis
Princess Margaret Hospital
Roberts Road
SUBIACO WA 6008

Dear A/Professor Davis

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

HREC REF 2014104EP

STUDY TITLE **Dietary proteins contribution to the insulin dose required to maintain post-prandial euglycaemia.**

The ethics application for the project referenced above was reviewed by the PMH Human Research Ethics Committee (HREC) at its meeting on 20/11/2014. It has been approved and the following documents have been approved for use in this project.

NEAF
WA Specific Module
Protocol Form 4B
Research Protocol Version 1 dated 23 September 2014
PMH Foundation grant approval letter
RDSS grant approval notification
Information Sheet for Youth Version 1 dated 23 September 2014
Information Sheet for Parents Version 1.1 dated 8 December 2014
Form of assent for Youth Version 1 dated 23 September 2014
Information Sheet for Adult Version 1 dated 23 September 2014
Consent form for parent Version 1 dated 23 September 2014
Consent form for adult participant Version 1 dated 23 September 2014

Approval of this project from PMH HREC is valid to and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only.

This project cannot proceed at any site until separate site authorisation has been obtained from the CE, or delegate, of the site under whose auspices the research will be conducted at that site.

The PMH HREC is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.pmh.health.wa.gov.au/development/resources/ethics.htm> or from the Ethics Office. Should you have any queries about the HREC's consideration of your project, please contact Ethics Office.

Please quote the above trial number 2014104EP on all correspondence associated with this trial.

Yours sincerely

A handwritten signature in black ink, appearing to read 'M. Salmon', with a long horizontal flourish extending to the right.

Dr Mark Salmon
Executive Director
Medical Services

10/12/2014

* The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans