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

Our Ref: 20160491.P

A/Professor Elizabeth Davis
Diabetes and Endocrinology
Princess Margaret Hospital
Roberts Road
Subiaco WA 6008

Dear A/Professor Davis

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

HREC REF **2016049EP**
STUDY TITLE **Insulin requirements to maintain post-prandial euglycaemia following consumption of a high protein/high fat meal**

The ethics application for the project referenced above was reviewed by the PMH Human Research Ethics Committee (HREC) at its meeting on 21/04/2016. It has been approved and the following documents have been approved for use in this project.

Protocol Form 4B Version 1.1 dated dated 04 April 2016
Lay Summary
Young Adult (12-17years) Information Sheet Version 1.2 dated 16 May 2016
Parent Information Sheet Version 2 dated 16 May 2016
Form of Consent (For Parent) Version 1.1 dated dated 04 April 2016
Form of Assent (For Adult Participant >18) Version 1.1 dated 04 April 2016
Form of Consent (For Young Adult 12-17) Version 1.1 dated dated 04 April 2016
Funding approval - JDRF dated 07 September 2015
Adult Participant (18+) Information Sheet Version 1.2 dated 16 May 2016

Approval of this project from PMH HREC is valid to 14/06/2019 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 Notification of withdrawn sites should also be provided to the HREC in a timely fashion.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 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 2016049EP on all correspondence associated with this trial.

Yours sincerely

Dr Mark Salmon
Director Clinical Services

14/06/2016

* 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

Government of Western Australia
Department of Health
North Metropolitan Area Health Service
Women and Newborn Health Service

CONDITIONS OF HREC APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of the approval will be deemed to be an acceptance of these conditions by all investigators involved in the research project:

1. The responsibility for the conduct of projects lies with the Coordinating Principal Investigator (CPI), all correspondence should be signed by CPI.
2. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The CPI must outline why the project approval should stand.
3. The submission of an application for HREC approval will be deemed to indicate that the investigator/s and any sponsor recognises the approving HREC is registered with the National Health and Medical Research Council (NHMRC) and that it complies in all respects with the National Statement on Ethical Conduct in Human Research and all other national and international ethical requirements. **The HREC will not enter into further correspondence on this point.**
4. A list of attendance at a specific meeting is available on request, but no voting records will be provided.
5. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC can result in the project being suspended or approval withdrawn.
6. The CPI will notify the HREC of any departures of named investigators. The CPI will also notify the HREC if any new investigators and/or sites join the project that will utilise the HREC's approval.
7. The CPI will inform the HREC about any changes to the project. The CPI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at any participating site until they have received HREC approval.
8. The CPI is responsible for reporting adverse events, indicating whether or not the project should continue. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports other than those outlined that are submitted to the HREC will be returned without acknowledgement. The HREC can request additional reporting requirements as a special condition of a research project.
9. Where a project requires a Data Safety Monitoring Board (DSMB) it is the CPI's responsibility to ensure this is in place before the commencement of the project and the HREC notified of this. All relevant reports from the DSMB should be submitted to HREC.
10. For projects where the site is acting as the sponsor (ie. investigator initiated project) it is the responsibility of the CPI to report serious and unexpected drug/device reactions, as well as other reactions/events to the Therapeutic Goods Administration (TGA). Please refer to TGA website for further information and the relevant forms (see http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf p71 for medications or p77 for devices).

11. If this project involves the use of an implantable device a properly monitored and up to date system for tracking participants is to be maintained for the life of the device in accordance with the National Statement section 3.3.22 (g).

12. The investigator is responsible for notifying the Therapeutic Drugs Administration of a device incident in accordance with the National Statement section 3.3.22 (g).

13. An annual report on an approved research project will be required on the anniversary date of the project's approval. HREC approvals are subject to the submission of these reports and approval may be suspended if the report is not submitted.

14. The HREC has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the HREC decides to undertake an audit for Quality Improvement purposes.

15. The HREC can conduct random monitoring of any project. The CPI will be notified if their project has been selected. The CPI will be given a copy of the monitor's report along with the HREC and Research Governance Office (RGO) at each site.

16. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the Committee's complaints procedures.

17. CPI are reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.

18. The duration of HREC approval for a project is 3 year (with the option of 5 years) from the date of approval. The date of approval expiry is stipulated in the HREC approval letter.

19. If the project is to continue beyond the stipulated approval expiry date a request for an extension should be submitted prior to that expiry date. One extension of 3 years can be granted but approval beyond this time period may necessitate further review by the HREC.

20. Once the approval period has expired, the CPI is required to submit a final report. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the CPI's ability to apply for approval for future projects.

21. If a project is suspended or terminated by the CPI, or a project sponsor, the CPI must immediately inform the HREC and the RGO at each site of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.

22. If a project fails to meet these conditions the HREC will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the HREC, the issues are not addressed the HREC approval will be withdrawn. The HREC will notify the RGO at each site within WA Health that work may no longer be conducted in relation to the project other than that concerning the participants safety.

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

Our Ref: 2016049EP

A/Professor Elizabeth Davis
Diabetes and Endocrinology
Princess Margaret Hospital
Roberts Road
Subiaco WA 6008

Dear A/Professor Davis

HREC REF **2016049EP**
STUDY TITLE **Insulin requirements to maintain post-prandial euglycaemia following consumption of a high protein/high fat meal**

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

Princess Margaret Hospital for Children - CAHS

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

Dr Mark Salmon
Director Clinical Services

14/06/2016

Government of **Western Australia**
Department of **Health**
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Research Governance Office

CONDITIONS OF SITE AUTHORISATION TO CONDUCT A RESEARCH PROJECT

The following general conditions apply to the research project authorised to be conducted at the site(s) nominated in the accompanying letter. The acceptance of the site authorisation will be deemed to be an acceptance of these conditions by all investigators involved in the research project at the nominated site(s).

1. The responsibility for the conduct of project at a site lies with the nominated Principal Investigator (PI) at that site, all correspondence should be signed by PI.

2. The PI will inform the Research Governance Office (RGO) about any changes to the project. The PI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at this site until they have received HREC approval for use at site(s).

3. The PI will notify the RGO of their inability to continue as PI at the site(s) and will provide the name and contact information of their replacement.

4. The PI will notify the RGO of any departures of named site investigators. The PI will also notify the RGO if any new site investigators join the project.

5. The PI is responsible for reporting site adverse events, using the standard forms available from the website. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports, other than those outlined, that are submitted will be returned without acknowledgement.

6. The annual report that is submitted to the HREC should also be submitted to the RGO. This should include the site specific information which should be completed by the site PI.

7. The site has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the site decides to undertake an audit for Quality Improvement purposes.

8. The site can conduct random monitoring of any project. The PI will be notified if their project has been selected. The PI will be given a copy

of the monitor's report along with the HREC and RGO.

9. Complaints relating to the conduct of a project should be directed to the RGO and will be promptly investigated according to the site Standard Operating Procedures.

10. The PI is reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.

11. Once the project has been closed at site, the PI is required to submit to the RGO a copy of the final report that is submitted to the HREC. This should include the site specific information which should be completed by the site PI. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the PI's ability to apply for approval for future projects.

12. If a project is suspended or terminated the PI must ensure that the RGO at site is informed of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.

13. If a project fails to meet these conditions the RGO will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the RGO, the issues are not addressed the site authorisation will be withdrawn.