



7 March 2017

Dr Carmel Smart
Paediatric Endocrinology & Diabetes
John Hunter Children's Hospital

Dear Dr Smart,

Re: Establishment of a safe insulin dosing schedule for high fat, high protein meals in individuals with type 1 diabetes using insulin pump therapy (16/12/14/4.01)

HNEHREC Reference No: 16/12/14/4.01

NSW HREC Reference No: HREC/16/HNE/606

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **14 December 2016**. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised Information Statement and Consent Form by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007)*, which the Committee is obliged to adhere to, include the requirement that the Committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **March 2018**.
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement:
Monitoring and reporting of safety for clinical trials involving therapeutic products

Hunter New England Research Ethics & Governance Office

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Email: HNELHD-HREC@hnehealth.nsw.gov.au

<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

May 2009

https://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf

- Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

| Document | Version | Date |
|---|-----------|------------------|
| NEAF [Submission Code: AU/1/8839216] | | |
| Protocol | Version 3 | 28 February 2017 |
| Information Sheet for Adults Participants | Version 4 | 3 March 2017 |
| Information Sheet For Adolescent Participants | Version 1 | 30 October 2016 |
| Information Sheet For Parents Of Participants | Version 4 | 3 March 2017 |
| Information Sheet For Child Participants | Version 1 | 30 October 2016 |
| Assent For Participants Aged 8-11 years | Version 1 | 30 October 2016 |
| Assent For Participants Aged 12-17 years | Version 1 | 30 October 2016 |
| Consent For Participants Aged 18+ years | Version 1 | 30 October 2016 |
| Consent For Parents Of Participants | Version 1 | 30 October 2016 |

Approval has been granted for this study to take place at the following sites:

- **Gosford Hospital**
- **John Hunter Hospital**
- **John Hunter Children's Hospital**

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

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **16/12/14/4.01** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Office

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