



Health

Hunter New England
Local Health District

2 April 2019

Dr Carmel Smart
Paediatric Diabetes
John Hunter Children's Hospital

Dear Dr Smart,

Re: 2019/ETH00068: Counting the carbohydrate, fat and protein. A novel smartphone insulin bolus calculator to simplify mealtime insulin dosing in Type 1 Diabetes

REGIS Project ID: 2019/PID00074

REGIS Application ID: 2019/ETH00068

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 **20 February 2019**. 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 (updated 2018)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been certified under the National Health and Medical Research Council's *National Certification Scheme for the Ethical Review of Multi-Centre Human Research*. 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 and following acceptance of the requested clarifications and revised HREA and recruitment documentation by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The National Statement, 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 for 5 years and 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 **April 2020**.
- 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.
- Adherence to the safety reporting requirements of the with the NHMRC Safety Monitoring and Reporting Guidance for Therapeutic Goods Trials (November 2016) available at https://www.nhmrc.gov.au/files/nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

Hunter New England Research Ethics & Governance Office

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

- 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.
- If the study has not been completed by **April 2024** a Renewal Application will be required.

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

Document	Version	Date
HREA [Application ID: 2019/ETH00068]	Version 4	2 April 2019
Response Letter		15 March 2019
Protocol	Version 3	Undated
Master Adolescent Participant Information Statement	Version 2	28 March 2019
Master Adolescent Consent Form	Version 1	21 January 2019
Master Adult Participant Information Statement	Version 2	28 March 2019
Master Adult Consent Form	Version 1	21 January 2019
Master Parent/Guardian Information Statement	Version 2	28 March 2019
Master Parent/Guardian Consent form	Version 1	21 January 2019
Victorian Specific Module		11 February 2019

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

- **John Hunter Children's Hospital, NSW**
- **St Vincent's Hospital Melbourne, VIC**

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 **2019/ETH00068** in all correspondence.

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

Yours faithfully



For: A/Professor A Vertigan
Acting Chair
Hunter New England Human Research Ethics Committee

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