



27 July 2018

Professor John Attia
Level 3, The Pod
Hunter Medical Research Institute

Dear Professor Attia,

Re: Zinc in Preventing the Progression of Pre-Diabetes (ZIPPeD Study) (18/07/18/3.03)

HNEHREC Reference No: 18/07/18/3.03
NSW HREC Reference No: HREC/18/HNE/179

Thank you for submitting the above protocol 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 **18 July 2018**. 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.

As part of the procedure for ethical approval of research involving humans in Hunter New England Health the above protocol was reviewed by the Clinical Trials Subcommittee, an advisory group of the Hunter New England Human Research Ethics Committee.

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 Protocol and Information Statement 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)*, to which the Committee is obliged to adhere, includes 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 **July 2019**.
- 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

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>

https://www.nhmrc.gov.au/files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

- 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
HREA [Submission Code: AU/1/B487311]		
Protocol	Version 2	23 July 2018
Zinc gluconate capsules (30mg elemental zinc) Investigator Brochure	Version 1	27 June 2018
Master Participant Information Statement	Version 2	23 July 2018
Master Participant Consent Form	Version 1	6 June 2018
Screening Questionnaire	Version 1	27 June 2018
Dietary Questionnaire © Copyright The Cancer Council Victoria	Version 2	2005
Participant Characteristics Questionnaire	Version 1	27 June 2018
Medical History Questionnaire	Version 1	27 June 2018
Physical Measures Questionnaire	Version 1	27 June 2018
Adverse Events Questionnaire	Version 1	27 June 2018
Unblinding (Control) Letter	Version 1	28 June 2018
Unblinding (Active) Letter	Version 1	28 June 2018

For the protocol: **Zinc in Preventing the Progression of Pre-Diabetes (ZIPPed Study)**
[Protocol Version 2 dated 23 July 2018]

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

- **Central Coast Local Health District**
- **Hunter New England Local Health District**

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 your site has been obtained.

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

Please quote **18/07/18/3.03** in all correspondence.

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.

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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