Government of South Australia
Health
Central Adelaide Local Health Network

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Human Research Ethics Committee

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ABN: 96 269 526 412

Approval Date: 15 January 2020

Dr Chinmay Marathe
Faculty of Health and Medical Sciences
UNIVERSITY OF ADELAIDE

Dear Dr Marathe

CALHN Reference Number: 12036

HREC Reference Number: HREC/19/CALHN/395

Project Title: Effects of acute hyperglycaemia on the slowing of gastric emptying induced by the 'short-acting' GLP-1 receptor agonist, exenatide BID in type 2 diabetes.

Human Research Ethics Committee APPROVAL

Thank you for submitting the above project for ethical and scientific review. The application was first considered by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) at its meeting held on 19 September 2019.

The CALHN HREC has reviewed all responses, and I am pleased to advise that the application has been granted full ethics approval. The project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* updated 2018.

The documents reviewed and approved include:

Document	Version	Date
HREA Application - AU/1/A1AA315		05 August 2019
Cover Letter		26 August 2019
Protocol	2	02 December 2019
Byetta Product Information		14 March 2017
Byetta Consumer Medicine Information	-	March 2017
Participant Information Sheet	2	02 December 2019
Consent Form	2	02 December 2019
Radiation Safety Report	-	02 August 2019
EPA Form	-	15 January 2020
Response to request for further information - email	-	15 December 2019

Sites covered by this approval:

Site	State	Investigator
Royal Adelaide Hospital	SA	CPI: Dr Chinmay Marathe

CALHN HREC approval is valid for 5 years from: **15 January 2020 to 15 January 2025**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the project must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. The CALHN HREC is certified by the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review. The CALHN HREC is the reviewing HREC for the purpose of this ethics approval. Any project sites that are not listed on this letter are not covered by this ethics approval. Any project sites that wish to be added must contact the CPI, who must formally request the additional sites to be added by CALHN HREC.
3. Researchers must notify the CALHN HREC of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
    a) adverse events which warrant protocol change or notification to research participants;
    b) changes to the protocol;
    c) changes to the safety or efficacy of the investigational product, device or method;
    d) premature termination of the project.

4. All all clinical trials approved by the CALHN HREC must comply with the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016)*. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.

5. The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.

6. Confidentiality of the research participants must be maintained at all times as required by law.

7. Adequate record keeping is important and must be maintained in accordance with Good Clinical Practice, NHMRC and state and national guidelines. If the project involves signed consent, researchers must retain the completed Consent Forms which relate to this project and a list of all those participating in the project to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years from completion of the project.

8. Approval is valid for **5 years** from the date of this letter after which an extension must be applied for.

9. **Annual Progress Reports must be submitted to the CALHN HREC, every 12 months on the anniversary of the above approval date**. The Coordinating Principal Investigator for all multi-site projects or the Principal Investigator for single site projects must provide reports of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of HREC approval. Continuation of ethical approval is contingent on submission of this report, due within 30 days of the approval anniversary. Failure to comply may result in suspension of the project.

10. **A Final Report must be submitted to the CALHN HREC on completion of the project and for all site closures.** The Coordinating Principal Investigator for all multi-site projects or the Principal Investigator for single site projects must provide a final report of the outcome for completed research projects and for all site closures. A copy of any published material must also be provided with the report, or following when available.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office: Health.CALHNResearchGovernance@sa.gov.au

The CALHN HREC is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the CALHN HREC's consideration of your project, please contact the CALHN HREC Support Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The CALHN HREC wishes you every success in your research.

Yours sincerely,

Ian Tindall
Chair, Human Research Ethics Committee
Central Adelaide Local Health Network

cc: Site Research Governance Officer