HREC Committee Secretariat:

Dr Tony Skapetis
Dental Graduate

Mrs Patricia Fa
Clinical Trials Pharmacist

Mrs Seema Manoj
Minutes Secretary

HREC Committee Members:

Dr Grahame Ctercteko
Medical Graduate – Colorectal Surgeon

Mr John Fisher
Lawyer

Prof Vicki Flood
Allied Health

Mr John McLeod
Layperson

Ms Sarah Melov
Clinical Midwife Consultant

Mr Sean Mungovan
Physiotherapist

Dr Christopher Ryan
Medical Graduate - Psychiatrist

Mrs Katherine Schaffarczyk
Nurse Educator

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Nursing – Community Health

Dr Howard Smith
Medical Graduate – Endocrinologist

Ms Jennifer Sullivan
Layperson

Ms Elizabeth Tran
Investigational Drug Pharmacist

Dr Christine Wearne
Clinical Psychologist

Research Office File No: (6255)

Project ID	2019/PID14831
Ethics Ref:	2019/ETH13240
Governance Ref:	2019/STE16999
	2019/STE17000

7 February 2019

Professor Ngai Wah Cheung
Department of Diabetes and Endocrinology
Westmead Hospital

Dear Prof Wah Cheung

Project title: SMART MUMS WITH SMART PHONES 2 (SMs2) Text messaging support for women after gestational diabetes

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 13 November 2019 following single ethical review of the above project at its meeting held on 12 November 2019.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.
This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this research project to be conducted at:

- Westmead Hospital - Coordinating Principal Investigator Professor Ngai Cheung
- Blacktown Hospital - Principal Investigator Dr Mark McLean
- Campbelltown Hospital - Principal Investigator David Simmons

The following documentation has been reviewed and approved by the HREC:

- HREA 2019/ETH13240, version 3 dated 14 January 2020
- Protocol, version 3 dated 14 January 2020
- Master Participant Information Sheet and Consent Form - version 1, dated 4 October 2019
- Baseline Questionnaire version 1 dated 30 September 2019
- Breastfeeding Survey version 1 dated 4 October 2019
- AAQ version 1 dated 4 October 2019
- CRF Baseline-Version 1 dated 22 September 2019
- Diet Survey version 1 dated 4 October 2019
- EPDS version 1 dated 10 October 2019

- General Questions version 1 dated 4 October 2019
- User Survey version 1 dated 4 October 2019
- SF12 version 1 dated 10 October 2019
- Stage of Change Ques Version 1 dated 30 September 2019
- MRFF round 3 2019 _Award letter_100519_Cheung.pdf

Please note the following conditions of approval:

- The Coordinating Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- For clinical trials of implantable medical devices only – The Coordinating Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- The Coordinating Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Coordinating Chief Investigator will provide to the HREC in the specific format via REGIS, proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project. .
- The Coordinating Chief Investigator must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format.
- HREC approval is valid for 5 years contingent upon submission of an annual report via REGIS.
- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
    1. Discussion of relevant aspects of the project with investigators, at any time,
    2. Random inspection of research sites, data or consent documentation,
    3. Interview with research participants or other forms of feedback from them, and
    4. Request and review reports from independent agencies such as a Data Safety Monitoring Board.
- If your research project is an interventional trial, please ensure it is registered on one of the clinical trial registries, eg http://www.actr.org.au.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Coordinating Chief Investigator.

In all future correspondence concerning this study, please quote Research Office File number ***(6255).*** The HREC wishes you every success in your research.

Yours sincerely

Mrs Patricia Fa
Secretary
WSLHD Human Research Ethics Committee