Queensland Government

Townsville
Hospital and Health Service

18th December 2017

Ms Mary Adu
College of Medicine and Dentistry
James Cook University

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bunmi.malauaduli@jcu.edu.au

Dear Ms Adu,

HREC Reference number: HREC/17/QTHS/148
Project title: Impact of Mobile Phone Diabetes Application Intervention on Diabetes Patients: a Randomized Controlled Trial

Thank you for submitting a response to the Townsville Hospital and Health Service Human Research Ethics Committee (HREC) on 12/12/2017 regarding the above project. The correspondence was considered by the HREC Chairperson and reviewers on 15/12/2017.

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's '*National Statement on Ethical Conduct in Human Research'* (NHMRC, 2007). The Townsville Hospital and Health Service HREC operates in accordance with the *'Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research'* (NHMRC, 2003); and the '*National Statement on Ethical Conduct in Human Research'* (NHMRC, 2007). Attached is the HREC composition with membership category and affiliation with the Hospital (Attachment I).

The Human Research Ethics Committee has granted approval of this research project. The research proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research 2007 (updated May 2015).*

Documents reviewed and approved:	**Version**	**Date**
Response letter		11.12.17
Participant Information Sheet and Consent Form	3.0	11.12.17
Response letter		10.10.17
Research Protocol	1.0	07.08.17
Letter of introduction		27.07.17
Questionnaire	1.0	07.08.17
Documents noted:	**Version**	**Date**
Application *(AU/1/75CF217)*		05.08.17
Data collection tool	1.0	07.08.17
Curriculum Vitae – M.Adu		07.08.17

The research project has ethical approval for the following sites:
Townsville Hospital and Health Service

Please note the following key dates for this study:
HREC approval expiry: 17/12/2022
Annual report due: 17/12/2018

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 CEO or Delegate of that site has been obtained.

If conducting this study in a Health Service, a copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form and supporting study documents for authorisation from the CEO or Delegate to conduct this research at the approved sites. Refer to the local THHS website for further information on Site Specific Assessment: https://www.health.qld.gov.au/townsville/tresa/index

Please note the following conditions of approval:

1. The Principal Investigator or study sponsor will report anything to the Committee which might warrant review of ethical approval of the project, including:
   a) Within 72 hours of becoming aware of the event:
      i. All significant safety issues and urgent safety measures taken as a response to the significant safety issue.
   b) Within 15 calendar days of a sponsor's decision:
      i. Notification of temporary halt of a study for safety reasons,
      ii. Early termination of a study for safety reasons.
   c) Within 15 calendar days of becoming aware of the event or report:
      i. Any unforeseen events that might affect the ethical acceptability of the project,
      ii. Any protocol violations and deviations from the study protocol that implicate participant consent, participant safety or data integrity,
      iii. If the project is discontinued at a site before the expected date of completion,
      iv. Where applicable, all industry safety monitoring and or Data and Safety Monitoring Board (DSMB) reports.

   Do not submit individual line listings or individual adverse event reports to the HREC.

2. The Principal Investigator will provide an **annual progress report** and a final report at the completion of the study in the specified format to the HREC. The final report should include a copy of the results and/or publication, if not available at the time of reporting these must be provided in a timely manner. For clinical trials the annual report must include a safety report including a clear summary of the evolving safety profile of the trial.

3. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project must be submitted first to the HREC for review, then to the relevant Research Governance Offices (RGO).

   Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project are to be submitted to the relevant RGOs only.

   Further advice on submitting amendments is available from https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec/amendments.

4. The HREC may undertake active monitoring of this research at any time. This may include random inspections of research sites, data, or consent documentation; and or interviews with research participants or other forms of feedback from them.

Should you require any additional information, please contact the HREC Coordinator on (07) 4433 1440 or TSV-Ethics-Committee@health.qld.gov.au. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec.

The HREC wishes you every success in your research.

Kind regards

A/Prof Nikola Stepanov PhD (Melb)
Chairperson
Townsville Hospital and Health Service
Human Research Ethics Committee

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