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Ms Sarah Melov

Clinical Midwife Consultant

Prof Vicki Flood Allied Health Research Office File No: (5835)

HREC Ref: AU RED HREC/18/WMEAD/365

SSA Ref: AU RED

7 May 2019

Letter amended 8 May 2019

Dr Katherine Phillips Department of Anaesthesia Westmead Hospital

Dear Dr Phillips

<u>Project title: Use of text messaging support to aid smoking cessation in patients presenting for surgery (TextPOP)</u>

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 26 September 2018 following single ethical review of the above project at its meeting held on 25 September 2018.

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 by you at:

• Westmead Hospital – Principal Investigator Dr Katherine Phillips

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

- HREA submission code AU/1/FA3833
- Protocol, version 5 dated 2 May 2019
- Participant Information Consent Form Main study, version 3 dated 7 May 2019
- Initial Visit, No version number dated 15 August 2018
- Follow up, No version number dated 15 August 2018

Please note the following conditions of approval:

• The 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.

- The 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.
- Proposed amendments to the protocol or conduct of the research which may affect the ethical acceptability of the project, must be provided to the HREC to review in the specific format. Copies of all proposed changes must also be provided to the research governance officer.
- The HREC must be notified, 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 granted for a period of 12 months and ongoing approval is contingent upon annual submission. Annual Reports for all studies should be submitted in November, they will be processed and presented to the HREC at their January meeting. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the investigators.

You are reminded that this letter constitutes *ethical approval only*. You must not commence this research project until separate authorisation from the Chief Executive or delegate has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to the Research Governance Officer as part of the Site Specific Assessment (SSA) application.

In all future correspondence concerning this study, please quote Research Office File number *(5835)*. The HREC wishes you every success in your research.

Yours sincerely

Mrs Patricia Fa

Secretary

WSLHD Human Research Ethics Committee

cc: Research Governance Officer