Research Office File No ***(4826)***

HREC Ref: *AU RED HREC/1/WMEAD/336*
SSA Ref: *AU RED SSA/1/WMEAD/381*

28 September 2016

Prof Alison Jones
University of Wollongong Faculty of Science,
Medicine and Health

Dear Prof Jones

Project title: "SMS SOS: Effectiveness of SMS text messages in improving survival and rehabilitation rates of deliberate self-harm patients and reducing re-presentation of DSH patients to hospital"

Thank you for submitting the above project which was considered by the WSLHD Human Research Ethics Committee at its meeting held on 27 September 2016.

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 **multicentre** research project to be conducted at:

- Westmead Hospital – Principal Investigator A/Prof Christopher Ryan
- Blacktown Mt Druitt Hospital – Principal Investigator A/Prof Naren Gunja
- Nepean Hospital – Principal Investigator Dr Anita Kotak

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

- NEAF submission code AU/1/D928213
- Protocol Version 1 dated 15 August 2016
- Master Participant Information and Consent Form Version 1, dated 17 August 2016

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, proposed amendments to the research 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 amendments when approved by the HREC must also be provided to the Research Governance Officer.
- 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 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.
- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
  - Discussion of relevant aspects of the project with investigators, at any time,
  - Random inspection of research sites, data or consent documentation,
  - Interview with research participants or other forms of feedback from them, and
  - 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.

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 that site has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any queries about the HREC's Terms of Reference, Standard Operating Procedures or membership, please contact the Acting Research Ethics Manager through the Research Office on 9845 8183 or emailing kellie.hansen@health.nsw.gov.au.

In all future correspondence concerning this study, please quote the Research Office File Number **(4826).**

The HREC wishes you every success in your research.

Yours sincerely

Mrs Kellie Hansen
Acting Research Ethics Manager
WSLHD Research & Education Network

cc Ms Margaret Piper, Research Governance Officer