18 August 2014

Professor Isabel Higgins
Nursing & Midwifery Research Centre
E Block
John Hunter Hospital

Dear Professor Higgins,

Re: An evaluation of the Aged Care Emergency (ACE) Program: Stage 2 (14/06/18/5.10)

HNEHREC Reference No: 14/06/18/5.10
NSW HREC Reference No: LNR/14/HNE/242

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has granted ethical approval for the following amendment requests:

- For the addition of Associate Professor Andrew Searles as a Principal Investigator;
- For the addition of Dr Rod Ling as a Principal Investigator;
- For the evaluation to now include a costing study;
- For two additional questions to be added to the interviews:
    - What are you doing as part of the ACE service?;
    - What is different in your role from before ACE was implemented in this service?
        - Time
        - Resources;
- For the Participant Invitation to Participate (Version 3 dated 8 July 2014); and
- For the Interview Guide (Version 2 dated 18 August 2014)

For the study**: An evaluation of the Aged Care Emergency (ACE) Program: Stage 2**

Approval from the Hunter New England Human Research Ethics Committee for the above study is given for a maximum of **3** years from the date of the approval letter of your initial application, after which a renewal application will be required if the study has not been completed. The above study is approved until **February 2017.**

Approval has been granted for this study to take place at the following sites:

Hunter New England Human Research Ethics Committee
Locked Bag 1
New Lambton NSW 2305
Telephone: (02) 49214950 Facsimile: (02) 49214818
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/research_ethics_and_governance_unit

- **Belmont District Hospital**
- **Calvary Mater Newcastle**
- **John Hunter Hospital**
- **Hunter Medicare Local**

The *National Statement on Ethical Conduct in Human Research (2007)* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above study be submitted at 12 monthly intervals. Your review date is **February 2015.** A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above study, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this study, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    - any serious or unexpected adverse events

        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.

        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Professional Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

        - Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.

        - Serious adverse events are defined as:

            - Causing death, life threatening or serious disability.
            - Cause or prolong hospitalisation.
            - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

    - Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above study does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Ethics and Governance Unit as soon as possible.

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The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote **14/06/18/5.10** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Professor M Parsons
Chair
Hunter New England Human Research Ethics Committee

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