



Mrs Katherine Rae
39 Laughton St
Chisholm ACT 2905

Dear Mrs Rae

ETH.10.17.233

The ACT Health Human Research Ethics Committee considered the proposed:

Evaluating the Effectiveness of Pressure Mattresses for People over 65 years in Community Health at its meeting of 6 November 2017.

I am pleased to inform you that, following further correspondence, the committee agreed the proposal satisfied the requirements for ethically acceptable research as per the National Statement on Ethical Conduct in Human Research and as such the application has been approved.

Approval includes:

- Response to feedback
- NEAF dated 11 October 2017, updated
- Research Proposal and Protocol, version 2 dated 23 November 2017
- Participant Information Sheet and Consent Form, version 1 dated 15 June 2017, updated
- Low-Risk Information Sheet (Consent by another person on behalf of the participant)
- Pressure Mattress Study Baseline Survey
- Pressure Mattress Study Follow-up Survey

I confirm that the ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2007 and is certified for single review of multi-centre clinical trials. ACT Health HREC operates in compliance with applicable regulatory requirements and the International Conference on Harmonization Guidelines on Good Clinical Practice.

I attach for your records an Outcome of Consideration of Protocol form.

Please note: this letter gives approval for ACT Health sites only. Please ensure appropriate approvals are in place at non-ACT Health sites.

Yours sincerely

A/Professor Paul Craft MPH FRACP
Acting Chair
ACT Health Human Research Ethics Committee

9 February 2018

ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE

Outcome of Consideration of Protocol

Submission No: ETH.10.17.233 **Date of Approval:** 9 February 2018

Project Title: Evaluating the Effectiveness of Pressure Mattresses for People over 65 years in Community Health

Submitted by: Mrs Katherine Rae

Your project was considered by the ACT Health Human Research Ethics Committee and Approved for a period of 5 years from 9 February 2018 to 9 February 2023

First Annual Review due: 15 October 2018

Conditions of Approval:

- At regular periods, and not less than annually, Principal Investigators are to provide reports on matters including:
 - unforeseen events that could affect the continued ethical acceptability of the project
 - proposed changes in the protocol
 - updates of the investigator brochures
 - continued compliance with approved consent procedures and updates of consent documentation
 - Data Safety Monitoring Board Reports (where applicable)
 - security of records
 - updated insurance coverage
 - compliance with other approved procedures.
- All published reports are to carry an acknowledgement stating:
 - Approved by ACT Health Human Research Ethics Committee on 9 February 2018



A/Professor Paul Craft MPH FRACP
Acting Chair
ACT Health Human Research Ethics Committee

9 February 2018