Participant Information Sheet

Study Title	Testing the Effectiveness of Pressure Mattresses for People over 65 years
Protocol Number	ETH.10.17.233
Principal Investigator	Katherine Rae
Research Site	ACT Health Community Care

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask the study team any questions you have and request any further information you need.

Why is this study being done?

The aim of this study is to compare how effective different types of specialised mattresses are at healing pressure injuries. We are looking to see if one type mattress helps these kinds of wounds heal faster than the other type of mattress.

Why have I been chosen?

You have been chosen to participate in this study because:

- you have a current pressure injury;
- you do not currently use a pressure mattress
- you live at home and;
- are over the age of 65

What is involved in the study?

This study has been based on current practice within ACT Health Community Care services for management of this kind of injury. The primary difference from current practice is wound photographs are taken more often and will be assessed by nurses who are separate to your care.

Participation in the study will include:

- *Allocation of a pressure mattress and cushion*. You will be expected to use the mattress each time you use your bed and the cushion for all times when you are sitting out of bed. You will have these items for the duration of your time participating in the study, after which they will be returned to the equipment provider.
  Please note: if you normally use an electric blanket, you will not be able to continue to use this with the pressure mattress as they can damage each other and pose a fire hazard.

- *Standard wound care provided by the Community Care Program Nursing.* This includes accessing your medical record as part of the nursing assessment and photographs of your pressure injuries at each treatment session to monitor wound healing. This may be as frequent as daily or second daily in the beginning but will reduce as your pressure injury heals. This may take place in your home or in a clinic.

- *Occupational therapy assessment*. This will include education of the management of pressure injuries as well as investigation into long term equipment needs if needed. This will occur early in the study, after consent has been received. This may take place in your home or in a clinic.

- *Completion of two surveys*, one at the beginning and one approximately 1-2 weeks after the mattress and cushion have been provided. These surveys will be investigating sleeping positions and habits, comfort and pain levels as well as thoughts and experiences about the allocated mattress. They will also briefly touch on your habits relating to common pressure injury prevention techniques, such as eating habits and personal hygiene.
  It is preferred that these surveys are completed online however arrangements can be made for those who do not have access to the internet. Please let the research team know if this is the case.

- The photographs taken of your wounds will be assessed by Tissue Viability nurses who will have no involvement in your care. These assessors will only know you based on your unique identifier and not by name.

- Your participation in this study will continue until either one week after your pressure injury has healed or eight weeks after you have been provided with the mattress, whichever comes first. Should you be removed from the mattress (eg you request removal of the mattress, go into hospital or experience other health complications that mean the mattress is no longer suitable for you) then you will be considered to have finished the study.

Why have I been chosen?

You have been chosen to participate in this study because:

- you have a current pressure injury;
- you do not currently use a pressure mattress
- you live at home and;
- are over the age of 65

Do I have to take part?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Should you choose not to participate, or to withdraw from the study, you will still continue to receive nursing and occupational therapy services as needed and an alternative

mattress and cushion will be arranged if required. Information that has been collected about you prior to your withdrawal will not be used in the data analysis unless you state otherwise. No new information will be collected or used after you have withdrawn from the study.

Are there any risks?

As this study is based on current practice, the risks associated with participating in this study are the same as if you were to receive this care outside of the study. There are no additional risks anticipated. As with all newly prescribed pressure mattresses, the provided mattress may make moving around in bed harder due to the properties of the mattress.

Are there any benefits?

If you agree to take part in this study, there may or may not be direct physical or psychological benefits to you. Your participation may help others in the future.

The results from this study will assist clinicians when prescribing these kinds of mattresses to people for pressure injury healing. The combined comments from the survey will allow clinicians to understand what things should be considered when prescribing mattresses.

What are the costs?

There will be no cost to you for participating in this study.

Financial disclosure

This study is being completed as part of a Doctorate of Philosophy (PhD) through the University of Canberra. There are no funding arrangements in place. No investigator or member of research staff will receive a personal financial benefit from your involvement in this study. The study clinicians declare no personal conflict of interest relevant to the undertaking of this study. Equipment provided has been loaned and remains the property of the equipment supplier.

Access to the results of the study

If you would like to be provided with a copy of the results at the completion of the study, please indicate this on the consent form. You will be posted a summary of the results once all the information has been collated. Please note this study is expected to take a few years for completion so this information sheet will likely be provided some time after you finish in the study.

In any publication, information will be provided in such a way that you cannot be identified. Results will be provided to you, if you wish.

What about confidentiality?

Your personal information will be protected throughout your participation within the study.

Your basic contact details (name, address and phone number) will be provided to the equipment supplier for the sole purpose of delivery and collection of the equipment. The supplier will not have access to any of your medical information.

All participating clinicians will be subject to the Privacy Act 1988, the Health Records (Privacy and Access) Act 1997 and the APS Code of Conduct.

Any clinical information will be stored electronically within secure ACT Health systems in adherence to Health Records (Privacy and Access) Act 1997 (Republication No 27) (ACT). This includes any written information as well as photographs.

Information for publication will either be collated with other participants or de-identified with the use of pseudonyms. If photographs are used in publication, any distinctive marks not relevant to the image, such as birthmarks or moles, will be removed from the photograph.

At the completion of the study, records will be de-identified and archived electronically within ACT Health servers and University of Canberra servers for seven years as per ACT Legislative requirements ("Health Records (Privacy and Access) Act 1997 (Republication No 27) (ACT)," 2016) after which it will be deleted.

Online survey providers

When using an overseas owned online survey provider, information is stored overseas and is subject to the laws and legislation of the country in which it is stored; this may be significantly different to Australian laws and legislation. As such, confidentiality of data entered into online surveys cannot be guaranteed by the study team.

If you have any questions please contact the research team

- Katherine Rae (Primary Researcher; ACT Health and University of Canberra)
  Telephone (02) 6205 1487
  Email: katherine.rae@canberra.edu.au OR katherine.rae@act.gov.au
- Asst Prof. Stephen Isbel (Research Supervisor; University of Canberra, Faculty of Health)
  Telephone (02) 6201 5246

Should you have any problems or queries about the way in which the study is conducted, and do not feel comfortable communicating with the staff conducting this survey, please contact: ACT Health Human Research Ethics Committee (ACTH-HREC), Level 6, Building 10, Canberra Hospital, Telephone: (02) 6174 7968 or ethics@act.gov.au

Consent Form for Participation in a Research Project.

I, _____ *(name of participant)*

of _____ *(address)*

have been asked to consent to participation in a research project entitled:

Testing the Effectiveness of Pressure Mattresses for People over 65 years

In relation to this Low-risk research study I have read the Participant Information Sheet and have been informed of the following points:

1. Approval has been given by the ACT Health Human Research Ethics Committee.

2. The aim of the study is to compare how effective different types of specialised mattresses are at healing pressure injuries

3. The results obtained from the study may or may not be of direct benefit to me

4. The study procedure will involve:

a) allocation of pressure equipment, to be used at all times

b) standard nursing including access to my medical record for the purpose of the nursing assessment and photographs on my pressure injury for monitoring of wound healing, which will be included in my clinical record.
- ☐ I consent photographs being taken for the purposes of this study
- ☐ I consent to de-identified photographs being used in publication

c) occupational therapy intervention, including education on pressure care and prescription of long term pressure equipment if required

d) completion of two online surveys investigating sleeping habits, comfort, pain levels, thoughts and experiences regarding the allocated mattress
- ☐ I will need assistance from the research team to access the online surveys

e) photographs of my pressure injury to be accessed and assessed by Tissue Viability nurses with no involvement in my care

f) completion of study once my wound has healed OR eight weeks after mattress provision OR should the need arise for my safety or preference

g) confidentiality will be assured within appropriate legislation and APS code of conduct with de-identified data being archived electronically within ACT Health and University of Canberra records for seven years before being deleted

h) my basic contact details (name, address and phone number) will be provided to the equipment supplier for the sole purpose of delivery and collection of the equipment.

5. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the research staff, I am aware that I may contact the ACT Health Human Research Ethics Committee Secretariat, Canberra Hospital, Yamba Drive, Garran ACT 2605 (ph: 6174 7968)

6. I can refuse to take part in this project or withdraw from it at any time without giving a reason

7. I understand that while the results of the research will be made accessible my involvement and my identity will not be revealed.

After considering all these points, I accept the invitation to participate in this study. I am not aware of any medical condition that would prevent my participation in this study.

☐ I would like to be notified of a summary of the results at the conclusion of the study

Name: (please print) _____ **Date:** _____

Signature (Participant) _____

Investigator: (please print) _____ **Date:** _____

Signature (Investigator) _____

If you have any questions please contact the research team

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