Participant Information Sheet for Low-Risk Research Project
(Consent by another person on behalf of the participant)

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

Background:

Under the *Powers of Attorney Act 2006* and the *Guardianship and Management of Property Act 1991,* consent for participation in low-risk research may be given by a person holding an enduring power of attorney, a guardian and a health attorney. A health attorney is defined under the second Act as a person who is either:

a) the domestic partner of the person concerned,
b) their carer or
c) a close relative or friend of the person

with priority to be given in the order listed. You cannot be a health attorney for a child or a person with impaired decision-making ability.

To consent to this research as a person holding an enduring power of attorney or a guardian you must have been given the power to consent to medical research matters if you were given that power since 1 September 2016. If you were given enduring power of attorney or became a guardian before 1 September 2016 you must have been given that power specifically in relation to medical treatment or other procedures in order to be able to consent to this research.

In consenting on behalf of another person to participate in this research you will need to indicate on the consent form under what category you are giving consent and that you understand the decision-making principles that apply.

Before you decide whether or not you wish your relative/loved one to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

No fee can be paid for your consent

You must not accept a fee or other benefit for consenting, or refusing to consent, to your relative/loved one taking part in this research.

What is the purpose of this study?

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 has my relative/loved one been invited to participate in this study?

Your relative/loved one has been chosen to participate in this study because:

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

What does this study involve?

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 the care of your relative/loved one.

Participation in the study will include:

- *Allocation of a pressure mattress and cushion*. Your relative/loved one will be expected to use the mattress each time they use their bed and the cushion for all times when they are sitting out of bed. They will have these items for the duration of their time participating in the study, after which they will be returned to the equipment provider.
  Please note: if they normally use an electric blanket, they 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 the medical record of your relative/loved one as part of the nursing assessment and photographs of your relative/loved one's 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 their pressure injury heals. This may take place at 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 at 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 relative/loved one's 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 cannot access to the internet. Please let the research team know if this is the case.

- The photographs taken of your relative/loved one's wounds will be assessed by Tissue Viability nurses who will have no involvement in their care. These assessors will only know them based on their unique identifier and not by name.

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

What if I don't want my relative/loved one to take part in this study or if I want to withdraw their participation later?

Participation in this study is voluntary. It is completely up to you whether or not your relative/loved one participates. If you decide your relative/loved one should not participate, it will not affect the treatment they receive now or in the future. Whatever your decision, it will not affect your or your relative/loved one's relationship with the staff caring for them.

Should you choose not to consent, or to withdraw from the study, your relative/loved one 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 your relative/loved one prior to their 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 them from the study.

New information about the use of pressure mattresses for healing of pressure injuries may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to have your relative/loved one continue in the study. If you wish to withdraw your relative/loved one from the study once it has started, you can do so at any time without having to give a reason.

Are there risks to my relative/loved one in taking part in this study?

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.

If you agree for your relative/loved one to take part in this study, there may or may not be direct physical or psychological benefits to them. 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.

Who is organising the research?

This study is being conducted by the study team headed by Katherine Rae. This study is being completed as part of a Doctorate of Philosophy (PhD) being completed through University of Canberra.

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.

How is this study being paid for?

Participation in this study will not cost you or your relative/loved one anything. Participants will not be paid for their involvement.

This study is being completed as part of a Doctorate of Philosophy (PhD). There are no funding arrangements in place. Equipment provided has been loaned and remains the property of the equipment supplier.

How will my relative/loved one's confidentiality be protected?

Your relative/loved one's personal information will be protected throughout their participation within the study.

Your relative/loved one's 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 their 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.

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.

What happens with the results?

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 your relative/loved cannot be identified. Results will be provided to you, if you wish.

What happens to my relative/loved one's treatment when the study is finished?

Decisions about your relative/loved one's continuing care will be made in consultation between you and their treating clinicians. At the end of the study, the pressure equipment provided will need to be returned to the equipment supplier however alternative equipment will be arranged if it is still required. Your relative/loved one will continue to receive nursing and occupational therapy services as needed.

What do I need to know before I make the decision to consent on behalf of another person?

You need to consider the following decision-making principles before you make the decision to provide consent for your relative/loved one to take part in this low-risk research**:**

a) Your relative/loved one's wishes, as far as they can be worked out, must be given effect to, unless making the decision in accordance with their wishes is likely to significantly adversely affect your relative/loved one's interests;
b) if giving effect to your relative/loved one's wishes is likely to significantly adversely affect their interests—you must give effect to their wishes as far as possible without significantly adversely affecting their interests;
c) if your relative/loved one's wishes cannot be given effect to at all—their interests must be promoted;
d) your relative/loved one's life (including their lifestyle) must be interfered with to the smallest extent necessary;
e) your relative/loved one must be encouraged to look after himself or herself as far as possible
f) your relative/loved one must be encouraged to live in the general community, and take part in community activities, as far as possible.

If your relative/loved one was participating in low-risk research before he or she had impaired decision-making capacity, it is presumed their wishes include to continue participating in the low-risk research.

Before you make a decision to consent you must consult with each carer of the person. However, you must not consult with a carer if the consultation would, in your opinion, adversely affect the person's interests. You are not limited in terms of who you consult about your decision to consent on behalf of your relative/loved one.

What should I do if I want to discuss this study further before I decide?

You are able to take this information away with you and discuss with your family, friends, treating doctor or any other person you choose. If you would like to know more at any stage, please do not hesitate to 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

Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the ACT Health Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this study, and do not feel comfortable discussing this with study staff, you may contact the Committee secretariat who is nominated to receive complaints about research projects. You should contact the secretariat on 02 6174 7968 or ethics@act.gov.au

Thank you for taking the time to consider this study.

If you wish to take part, please sign the attached consent form.

This information sheet is for you to keep.

Consent Form for Participation in a Research Project
(Consent by another person on behalf of the participant)

Low- Risk Research Only

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

On behalf of _____ (*name of person for whom consent is provided)*

I, _____ *(name of person providing consent)*

Being:

a person with Enduring Power of Attorney in relation to the person named above ☐ YES ☐ NO

OR

a guardian of the person named above ☐ YES ☐ NO

OR

a health attorney for the person named above ☐ YES ☐ NO

and if a heath attorney being

- the domestic partner of the person concerned, OR ☐ YES ☐ NO
- their carer, OR ☐ YES ☐ NO
- a close relative or friend of the person ☐ YES ☐ NO

(if you fit in more than one category tick the higher category on the list of health attorney options)

have READ and UNDERSTOOD the information sheet, considered the decision-making principles, and agree to the participation of the person named above in the low-risk research described in that information sheet, namely *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 relative/loved one's 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 my relative/loved one taking part in this project or withdraw them from it at any time without giving a reason and without affecting their medical care or any other service or treatment they are receiving.

7. I understand that while the results of the research will be made accessible my relative/loved one's involvement and their identity will not be revealed.

8. I have not accepted a fee or other benefit for consenting or refusing to consent to this research

9. I am not involved in or connected to this research except with respect to the participation of the person on whose behalf I am giving consent

After considering all these points, I accept the invitation for my relative/loved one to participate in this study. I am not aware of any medical condition that would prevent their 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 (Person providing consent) _____

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

Signature (Investigator) _____

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