Delete this line, then print on Trust/Hospital headed paper

PRESSURE 2

Pressure **RE**lieving **S**upport **SU**rfaces: a **R**andomised **E**valuation 2

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study called PRESSURE 2. The study is comparing two different types of mattresses which are commonly used in hospitals. Before you decide if you want to take part, we would like to explain why the research is being done and what the study will involve.

Please read this information carefully and discuss it with others if you like. A clinical research nurse or registered healthcare professional will also talk to you about the study and can answer any questions.

This document is split into two parts:

- Part 1 tells you about why we are doing the study and what will happen to you if you decide to take part.

- Part 2 gives you more detailed information about what the study involves.

Please take time to decide whether or not you wish to take part.

How to contact us

If you have further questions about this study, please talk to

<<Enter PI, nurse/registered healthcare professional name >>

<< Contact details for site>>

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study will compare two types of mattresses which are already widely used in hospitals to help prevent pressure ulcers. The mattresses are called High Specification Foam and Alternating Pressure. Alternating Pressure mattresses are made up of pockets of air which inflate and deflate at different times to help relieve the pressure on your skin. They are powered by electricity and make a small amount of noise. High Specification Foam mattresses (with no moving parts) are specially designed to distribute weight better and are routinely used for most patients in hospitals.

We would like to find out which mattress is best at helping to prevent pressure ulcers in hospitals and community based care settings for patients like you during your stay in hospital (so you won't need the mattress at home when you leave hospital). We will also be looking at how quickly existing pressure ulcers heal, patients' quality of life and how cost effective the mattresses are.

What is a pressure ulcer?

A pressure ulcer (sometimes called a bedsore) is an area of damaged skin, usually caused by being in one position or unable to move a part of the body for a long period of time. They are often caused by having to stay in bed due to another illness or injury. Special mattresses are one of the things used to try and prevent pressure ulcers occurring. Pressure ulcers vary in size and severity from a small red patch to deeper wounds: they can be painful and have a big impact on patients. This trial is an important part of finding out how pressure ulcers can be prevented.

Why have I been chosen?

You have been approached because you are over 18, you are expected to be in hospital for a few days or more and a nurse has identified you as having at least **one** of the following factors:

1. You have reduced mobility (e.g. you find it difficult to get out of bed and need help to move around).
2. You already have the early signs of a pressure ulcer.
3. You said an area of your skin feels sore/painful and may be due to lying in bed or sitting in the chair.

What will happen to me if I choose to take part?

If you decide to take part you will be asked to sign a consent form.

A clinical research nurse or registered healthcare professional will ask you some questions about your health, discuss and complete some health questionnaires with you and examine your skin. This will involve looking at areas of your body where pressure ulcers occur most

commonly, including your buttocks, heels, elbows, hips and lower back. If you already have a pressure ulcer the clinical research nurse or registered healthcare professional will measure it by drawing around the area onto a clear sheet.

You will then be given one of the mattresses and asked to sleep on that mattress for the rest of your hospital stay. You won't be able to pick which mattress you are given as it will be selected for you at random. However you, your family or any member of your healthcare team can ask for a change if you decide that you don't like sleeping on that mattress. Your care will continue as normal throughout the trial.

How is my condition monitored?

Every week day that you stay in hospital, a clinical research nurse or registered healthcare professional will check that you are still on the correct mattress. If you are on an Alternating Pressure Mattress, they will also check that it is working properly. You will not be disturbed when they make these checks. The clinical research nurse or registered healthcare professional will visit you twice a week to check your skin to see if any pressure ulcers have developed and to check how any existing pressure ulcers are healing. At two visits the clinical research nurse or registered healthcare professional will talk to you about your health and re-do some of the health questionnaires to see if anything has changed.

If you are in hospital for longer than 30 days, the clinical research nurse or registered healthcare professional will visit you once a week to look at your skin until;

1. your mobility has improved and are unlikely to develop a pressure ulcer
2. you are discharged from hospital or
3. up to a maximum of 60 days;

As soon as one of these conditions is met your participation in the main part of the PRESSURE 2 trial will be complete. There will be one final follow up visit 30 days after the date you complete the main part of the trial. With your permission, this may mean the clinical research nurse or registered healthcare professional visiting you at home to look again at your skin and re-do the health questionnaires.

Photographs

If the clinical research nurse or registered healthcare professional finds a pressure ulcer then he / she will ask to take a photograph of it. They will always ask your permission before taking a photograph and you can say no at any point.

If you would prefer not to be photographed then you can opt out of photography, but still continue with other parts of the trial. The photographs will only be of your skin and pressure ulcer (not your face) so you will not be identified from the photographs.

A small selection of patients in the trial (1 in 10) will be visited by another senior nurse/registered healthcare professional (an expert in skin damage). If you are chosen, the senior nurse/registered healthcare professional will check your skin to see if there are any pressure ulcers, photograph an area of skin on your torso (for example your back or your buttocks) and one of your limbs (for example your heels). The photographs will be looked at by pressure ulcer experts who will not know what mattress you have been given.

Do I have to take part?

No. Your participation in PRESSURE 2 is completely voluntary and you may withdraw your consent to take part at any time, without giving us a reason. If you decide not to take part then your care will not be affected in any way.

If you decide to take part you will be given this information to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have a witness (e.g. a friend, a family member, or member of your healthcare team) to complete the written part of the consent for you. The witness will only act to help you carry out your wishes – you are free to change your mind at any time.

What are the possible disadvantages and risks of taking part?

As both mattresses are already widely used and have been tested for safety, there are no anticipated risks involved. However we are asking you to give up some of your time to take part. The clinical research nurse or registered healthcare professional will look at your skin, including intimate areas such as your buttocks and your lower back, and with your permission these areas may be photographed. You can opt out of this part if you prefer not to be photographed.

What are the possible benefits of taking part?

In addition to any skin inspections which the nurses on your ward will do as part of your routine care, a qualified clinical research nurse/registered healthcare professional with enhanced expertise in clinical skin assessment will also inspect your skin regularly for any signs of damage. If a pressure ulcer is found by the clinical research nurse/registered healthcare professional then your healthcare team will be informed immediately so that it can be treated quickly. Information from this study will help us to improve pressure ulcer prevention in the future and ultimately benefit other patients.

Will my taking part be kept confidential?

Yes. If you decide to participate in PRESSURE 2 the information collected about you will be handled in accordance with the consent that you have given and also the 1998 Data Protection Act. Please refer to Part 2 for further details.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making a decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point. If you decide to withdraw it will not affect the standard of care you receive. If you withdraw consent during the trial, any information we have collected about you up to that point will be kept, unless you request otherwise.

What if there is a problem?

It is very unlikely that you will come to any harm as a result of taking part in this study, as both types of mattresses are already used widely across the NHS every day. If you have a concern about any aspect of this study, you should ask to speak with your nurse or doctor. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details about how to complain can be obtained from staff on the ward or by contacting your local Patient Advice and Liaison Service (PALS) http://www.pals.nhs.uk/ or Patient Advice & Support Service (PASS) (Scotland).

In the unlikely event that you are harmed by taking part in this research project, compensation arrangements are in place. If you have grounds for legal action you may have to pay your legal costs. Any claims will be subject to UK law and must be brought in the UK.

Will my taking part in this study be kept confidential?

Yes. The hospital team will record some personal details to allow you to be followed up in hospital and at home. This will include your name, NHS number, hospital number, ward, address and telephone number. These details will be recorded on a paper research form and will be kept securely in a locked cupboard in a locked room.

The Clinical Trials Research Unit (CTRU) at the University of Leeds will receive your signed consent form (subject to your agreement) with your name, date of birth and NHS number (to check that you have not already been registered for the study). No other personal information about you will leave the hospital. You will be allocated a study number, which will be used along with your date of birth and initials to identify you on study documents but your name will not be entered onto the trial database. The CTRU will also receive the clinical and questionnaire information collected about you. This will be anonymised, kept strictly confidential and will be entered onto a secure database in accordance with the 1998 Data Protection Act. The anonymised information collected about you may be shared with other research teams to answer new research questions in the future. However your name and other personal details will not be shared.

In addition any photographs taken will be transferred immediately by secure email and stored on a secure database at the CTRU. Once confirmation of receipt is received by the clinical research nurse or registered healthcare professional, the photographs will be deleted from the

camera straightaway. The photographs will only be used for analysis and will be kept for a period of 5 years before being destroyed.

Involvement of your healthcare team

Subject to your agreement, your GP and your hospital Consultant (if applicable) will receive a letter letting them know that you are taking part in the study.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual patients will be identified. If you would like to obtain a copy of the published results, please ask a member of the research team.

Who has organised and funded the study?

PRESSURE 2 is being funded by the National Institute for Health Research and is being organised by the Clinical Trials Research Unit at the University of Leeds.

Who has reviewed the study?

The study has been reviewed by the NHS National Institute for Health Research before funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This committee exists to protect the safety, rights, wellbeing, and dignity of patients (Ethics ref: **13/YH/0066**). This research has also been reviewed by patients and carers.

Further information about research

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations in the UK) have published a booklet entitled 'Understanding Clinical Trials'. For a copy contact UKCRC: Tel: 0207 670 5452 or visit their website www.ukcrc.org

Delete this line, then print on Trust/Hospital headed paper

Participant ID:	Initials:
Date of Birth:	NHS/Hospital Number:
ISRCTN:	Principal Investigator:

PRESSURE 2
PARTICIPANT CONSENT FORM

Please initial each box

1. I confirm that I have read and understand the information sheet (version 6, 25.09.15) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the study and in some cases further information about any unwanted effects of my treatment may need to be collected by the study team. ☐

3. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly. ☐

4. I understand that the clinical research nurse or registered healthcare professional will keep secure records at the hospital which will allow me to be followed up in hospital and at home (including name, NHS number, hospital number, ward, address and telephone number). ☐

5. I agree to allow any information or results arising from this study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous wherever possible. ☐

The following point is OPTIONAL. Even if you agree to take part in this study, you do not have to agree to this section.

	Yes	No
6. I agree to allow the clinical research nurse, registered healthcare professional or senior expert nurse to take photographs of pressure ulcers (where present) and parts of my body that are vulnerable to the development of pressure ulcers, including both left and right buttocks and the lower back region.	☐	☐

7. I agree to a copy of this Consent Form, containing my name, date of birth and NHS number being sent to the CTRU. Your NHS number will be used to ensure that you have not already been registered for this study. ☐

8. I agree for my GP and hospital Consultant to be notified of my participation in this study. ☐

9. I agree to take part in the study. ☐

Patient:
Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the study to the above named patient and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……

(If used)Translator:

Signature……

Name (block capitals)……

Date……

Witness:
I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)