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PRESSURE 2

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

NOMINATED CONSULTEE INFORMATION SHEET

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

Invitation to be a nominated consultee

- We are inviting you to take the role of *nominated consultee* for a patient who is being invited to take part in a research project called PRESSURE 2. The study is comparing two different types of mattresses which are commonly used in hospitals.
- Before you decide whether or not you are willing to take on this role, we want you to understand what this involves.
- Please read this information leaflet carefully and take time to decide whether you are willing to take on this role.
- You are free to decide whether or not to take this role. If you choose not to, this will not affect your employment in any way.
- If you decide to take this role you should keep this information sheet for future reference.
- Ask us if anything is unclear, or if you would like more information.

What is a nominated consultee?

A nominated consultee is a staff member/other professional who advises on a patient's potential participation in a research project, when that person has been assessed to lack capacity to make an informed decision themselves.

They are appointed where the potential participant does not have a family member or close friend who is able or willing to act as a consultee.

What does a nominated consultee need to do?

A nominated consultee provides **advice** to the researcher about a potential participant's wishes and feelings in relation to the project and whether he or she should join the study.

A nominated consultee provides advice on whether, in the nominated consultee's opinion, based on their knowledge of the potential participant, the potential participant will be content to take part and whether participating might upset them.

A nominated consultee gives their opinion on what the potential participant's past and present wishes and feelings would have been about taking part in the study.

At any stage during the study, a nominated consultee should also advise the researchers if they feel the participant no longer wishes to take part in the research.

A nominated consultee is **not** asked to provide consent for or on behalf of the potential participant.

A nominated consultee is not allowed to be involved in any way in the research taking place in the care setting.

What if I don't feel able to take on this role?

If you feel unable to give advice about this, please say so. This will not affect your employment or the potential participant's future involvement in the study.

We will work with the ward staff/consultants to identify another staff member to approach with regard to this role.

If I agree to take this role, what do I need to do?

We would like you to consider the study information sheet, provided, and what you know of the wishes and feelings of the patient you are being asked to advise on, in terms of participating in research.

We would like to know whether or not you feel he/she would have agreed to join the study, if he/she had been able to decide.

Your advice should be based on your knowledge of the above person and their past and present views or feelings, not on your own views of research in general or this project.

In deciding on what you think the above person's wishes would be if they had capacity, you should attempt to seek the views of the person, and also the views of their family or friends who may be unwilling or unable to act as a consultee.

You may, where appropriate, also seek the views of other colleagues who have an interest in the person's welfare, **but who won't be involved in the research themselves**.

After appropriate consultation we would like you to complete the attached declaration form indicating whether you feel the named person would or would not have wished to participate.

If the potential participant is recruited to the study and during the course of the study you feel they have changed their mind about taking part, or that taking part is causing them distress, then you should tell one of the researchers.

Questions?

If you have any questions or would like more information, you can speak to the Researcher, whose details can be found on page 3 of this information sheet.

This section is split into two parts:

- Part 1 tells you about why we are doing the study and what will happen if the patient takes part.

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

Please take time to decide whether or not you think the patient should 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. 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 pressure on the 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 (so the patient won't need to take the mattress home with them when they 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 has this patient been chosen?

The patient has been approached because he/she is over 18, is expected to be in hospital for a few days or more and a nurse has identified that the patient as having at least **one** of the following factors:

1. Reduced mobility, (e.g. the patient finds it difficult to get out of bed and needs help to move around)
2. They have the early signs of a pressure ulcer .
3. Soreness or pain in one of the areas which it is common to get a pressure ulcer.

What will happen if I decide the patient should take part?

If you decide the patient should take part then you will be asked to sign a Nominated Consultee Declaration Form. This is to show you have been consulted about the research and are happy for the patient to be part of the study.

A clinical research nurse or registered healthcare professional will ask you some questions about the patient's health, discuss and complete some health questionnaires with you and examine the patient's skin. This will involve looking at areas of his/her body where pressure

ulcers occur most commonly, including buttocks, heels, elbows, hips and lower back. The clinical research nurse or registered healthcare professional will fill out the questionnaires but will be happy to show them to you. If the patient already has a pressure ulcer the clinical research nurse, registered healthcare professional or ward nurse will measure it by drawing around the area onto a clear sheet.

The patient will then be given one of mattresses to sleep on for the rest of their hospital stay. You won't be able to pick which mattress they are given, as it will be selected for them at random. However, you or the patient, their family or any member of the patient's healthcare team can ask for a change at any time. The patient's care will continue as normal throughout the trial.

How is their condition monitored?

Every week day that the patient stays in hospital, a clinical research nurse or registered healthcare professional will check that they are still on the correct mattress. If the patient is on an Alternating Pressure Mattress, they will also check that it is working properly. The patient will not be disturbed to make these checks.

The clinical research nurse or registered healthcare professional will check the patient's skin twice a week 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 re-do some of the health questionnaires to see if anything has changed. If the patient is in hospital longer than 30 days, the clinical research nurse or registered healthcare professional will visit them once a week to look at their skin until;

1. Their mobility has improved and they are unlikely to develop a pressure ulcer
2. They are discharged from hospital
3. Up to a maximum of 60 days.

As soon as one of these conditions is met the patient's participation on the main part of the Pressure 2 trial will be complete. There will be one final follow up visit 30 days after the date the patient completes the main part of the trial. With your permission this may mean the clinical research nurse or registered healthcare professional visiting the patient at home to look at the patient's skin again and repeat 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 for the patient not to be photographed then you can opt out of this part of the trial but still continue with other part of the trial.. The patient can also refuse at any time. The photographs will only be of the patient's skin and pressure ulcer (not their face) so they will not be identified from the photographs.

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

Does the patient have to take part?

No. Taking part in Pressure 2 is entirely voluntary. It is up to you to decide whether or not you feel it is appropriate for them to take part. If you are interested we will discuss the study with you and go through this Information Sheet. If you agree for the patient to take part you will be asked to sign a Consultee Declaration Form to show that you have been consulted about the patient participating in the study and have agreed it is appropriate for them to take part. You will be given a copy of this Information Sheet and of the signed Consultee Declaration Form to keep.

If you agree for the patient to take part you are free to change your mind and withdraw them from the study at any time, without giving a reason. This will not affect the standard of care they receive.

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 the patient to give up some of their time to take part. The study does involve a clinical research nurse or registered healthcare professional looking at their skin; this includes intimate areas such as their buttocks and lower back and with your permission these areas may also be photographed. You can opt out of this part of the trial if you think the patient would prefer not to be photographed.

What are the possible benefits of taking part?

In addition to any skin inspections which the nurses on the ward do as part of routine care a qualified clinical research nurse or registered healthcare professional with expertise in skin assessment will inspect the patient's skin regularly for any signs of damage. If a pressure ulcer is found by the clinical research nurse or registered healthcare professional then the patient's 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 taking part be kept confidential?

Yes. If you decide you would like the patient to participate in PRESSURE 2 then the information collected about them will be handled in accordance with the assent 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, please continue to read the additional information in Part 2 before making a decision.

Part 2

What will happen if I don't want the patient 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 you want to withdraw the patient from the study, it will not affect the standard of care they receive. If the patient withdraws consent during the trial, any information we have collected about them up to that point will be kept, unless you request otherwise.

What if there is a problem?

It is very unlikely that the patient 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 a nurse or doctor at the hospital. 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 the patient is 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 taking part in this study be kept confidential?

Yes. The hospital team will make a note of some of the patient's personal details to allow the clinical research nurse or registered healthcare professional to monitor them in hospital and follow them up at home. This will include their 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 copy of the Consultee Declaration Form you sign, which will include your name and the patient's name, date of birth and NHS number. They will check that the Consultee Declaration Form has been signed and dated properly and also use the patient's NHS number to ensure that the patient hasn't already been registered on to the study prior securely filing the form. No other personal information about you or the patient will leave the hospital. The patient will be given a study number, which will be used along with their date of birth and initials to identify them on study documents but your names will not be entered onto the trial database.

The CTRU will also receive the clinical and questionnaire information collected about the patient. This will be anonymised, kept strictly confidential and entered onto a secure database in accordance with the 1998 Data Protection Act. The anonymised information collected about the

patient may be shared with other research teams to answer new research questions in the future. However their 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 the patient's healthcare team

With your permission, the patient's GP and hospital Consultant (if applicable) will receive a letter letting them know that they 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 the contact person named on the first page of this information sheet.

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 (**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

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

PRESSURE 2

NOMINATED CONSULTEE DECLARATION FORM

Please initial each box

1. I confirm that I have been consulted about the patient's participation in the PRESSURE 2 study and have read and understood the information sheet (version 6, 25.09.15). I have had the opportunity to ask questions and have had these answered satisfactorily. ☐

2. I understand that the patient's participation is voluntary and that I am free to withdraw them from the study at any time without their medical care or legal rights being affected. ☐

3. I understand that if I withdraw the patient from the above study, the data already collected from them will be used in analysing the results of the study unless I specifically withdraw consent for this. ☐

4. I understand that relevant sections of the patient's healthcare records and data collected during the study may be looked at by authorised individuals from the study team, where it is relevant to their study participation. The Sponsor or other regulatory bodies may also access the patient's healthcare records in order to check that the study is being carried out correctly. ☐

5. I understand there will be secure storage of the patient's personal information (both paper and electronic) for the purposes of this study. This information will include name, NHS number, hospital number, ward, address and telephone number. I understand that any information that could identify them will be kept confidential and that no personal information that could identify them will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study. ☐

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

Please initial

Yes ☐ No ☐

6. I agree to allow the clinical research nurse, registered healthcare professional or senior expert nurse to take photographs of the patients pressure ulcers (where present) and parts of the patients body that are vulnerable to the development of pressure ulcers, including both left and right buttocks and the lower back region.

7. I understand that information and results arising from this study may be used to develop new research. ☐

8. I understand that a copy of this Nominated Consultee Declaration Form, containing the patient's name, date of birth and NHS number, will be passed to the Clinical Trials Research Unit (University of Leeds), where it will be filed securely. The patients NHS number will be used to ensure he/she has not already been registered on the study. ☐

9. I understand that the patient's GP and hospital consultant will be notified of the patient's participation in this study. ☐

10. In my opinion the patient would have no objection in taking part in this study ☐

_____
Name of Patient

_____ _____ _____
Name of Consultee Date Signature

Relationship to patient: _____

I have given written information and a verbal explanation to the consultee named above who has freely given their Declaration for the patient to participate.

_____ _____ _____
Name of Person Taking Consent Date Signature

1 copy for consultee 1 for patient records; 1 copy CTRU; original stored in Investigator Site File