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**If you have any questions about the HIDDEN study, please contact:**

To be confirmed

**Participant Information Sheet. The HIDDEN Study: Hospice Inpatient Deep Vein Thrombosis DEtectioN Study**

**We invite you to take part in a study**

 Before you decide whether to take part, it is important that you understand why this study is being done and what it will involve.

 Please take the time to read this leaflet carefully and decide whether you would like to take part. Discuss it with others if you wish.

 It is up to you to decide whether you would like to take part. Saying no will not affect the care you receive.

 Our contact details are included on this leaflet if you would like to ask us questions about the study.

The HIDDEN study: the essentials

 We want to find out how many patients admitted to hospices have a blood clot in their leg veins, known as a deep vein thrombosis (DVT).

 We would like to scan your legs using a bedside ultrasound scanning machine. We will do this once upon admission and then once a week while you are in the hospice.

 We will also ask you about your symptoms, your condition and medications.

 This study is being sponsored and coordinated by the University of Hull.

1 Why is this study being done?

 We want to find out how many patients admitted to hospices have a DVT, and how many develop a DVT whilst in the hospice. This information will help guide palliative care doctors and nurses in the best use of treatments to prevent a DVT and control symptoms from a DVT which might or might not include treating the DVT itself. This study will also help us understand better if a DVT should be treated or not.

2 Why am I being asked to take part?

You have been invited to take part in this in this study because you have been admitted to one of five participating hospices from around the UK.

3 What do I need to know about the HIDDen study?

This information sheet should tell you what you need to know, and you can ask the research team if you have any further questions. Please also discuss the study with family or friends if you wish.

We will ask you to decide whether to take part in this study within your first 24 hours of admission if possible. This is because we need to arrange to scan your legs within the first day or two of your admission if you wish to take part.

The Chief Investigators of this study are Professor Miriam Johnson and Dr Clare White. Both doctors are consultants in palliative medicine working with patients in Yorkshire and Northern Ireland, respectively.

The University of Hull will act as sponsor for this study. The study is funded by the National Institute for Health Research, Research for Patient Benefit.

4 What will I need to do if I take part?

We will ask you to sign a consent form to participate.

You will then be asked brief questions about your illness, medications and symptoms. We will not ask you to have any special blood tests. The nurse will also examine your legs briefly.

The next stage will involve you being scanned by an ultrasound scanner at your bedside by trained nurses. This is a similar machine to what is used to scan people having a baby and will not be painful. The scan will take approximately 10 minutes to do both legs and will be performed as soon as possible after admission. We will share the scan results with your doctor only if requested; that is, only if your doctor would order a DVT scan anyway as *part of your usual care*. These procedures will be repeated every week if you are still in the hospice and happy for us to do so.

The answers you give, the examination and scan result will help to determine the presence of new or changing symptoms and signs of blood clots in the legs or elsewhere.

5 What are the benefits and disadvantages of taking part?

The study will not alter your usual treatment in any way and there is no payment for taking part in the study. However, we hope that the results of this study will help us find a way to treat patients who are admitted to a hospice who are at risk of developing a DVT.

We do not anticipate that taking part in this study will cause you any harm. However, for any reason, during the study, you may withdraw at any time without affecting your care in any way.

6 Is there anything else I need to know?

Changing Your Mind

You do not have to take part in the research if you do not wish to do so. If you do decide to take part, you are free to withdraw from the study at any time, either before, during or after the study. If you decide not to take part, or to withdraw at any stage, you may do so. You do not have to give a reason. Your current or future medical care would not be affected in any way.

In this situation, we would not collect any further information, but anonymised study information already collected would be used a part of the study results.

Confidentiality

All information which is collected about you during the time of the study will be kept strictly confidential. Any information that could identify you, for example, your name or address, will be removed.

If you agree to take part, we will let your GP know.

Once this study is completed and reported, other genuine researchers might request access to the anonymous data to answer other clinical questions. The consent form will include a specific question about this to make sure you are happy with this.

Data protection

Any confidential information, will be stored in a safe place for up to five years after the end of the study. The written information will then be destroyed, in accordance with the Data Protection Act 1998.

Study results

The results of this study may be shown at medical meetings and submitted to medical journals for publication. You will not be identified in any way in any report or publication about this study.

Where possible, summary reports and publications will be made available to the general public on the study co-ordinator’s website. If you would like to find out about the results of the study please contact us using the details provided at the end of this leaflet.

What if there is a problem?

If you have a concern about any aspect of this study, please call or write to the researchers who will do their best to answer your questions (see contact details at end of leaflet). Any complaint about the conduct of the study will be addressed. If you remain unhappy and wish to make a formal complaint, you can firstly contact the study sponsor (University of Hull, undergoing approvals) at (email to be confirmed). You can also write to them at the following address:

To be confirmed

Alternatively you could contact the concerns team for [INSERT HOSPICE NAME] on [INSERT TELEPHONE NUMBERS] or alternatively email them on [INSERT EMAIL ADDRESS]. You can also write to them at the following address:

[INSERT POSTAL ADDRESS]

7 What do I do now?

If you would like to take part in the HIDDEN study, or would like more information about the study, please talk to the research nurse or doctor. If you do not want to take part in the study then you do not need to do anything further.

Thank you for taking the time to read the information and consider taking part in this study.

8 How can I contact the research team?

If you would like any further information, please contact us.

HIDDen Research team To be confirmed