*(To be printed on local hospital headed paper)*

**IRAS ID: 306352**
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**HIDDEN2: PARTICIPANT INFORMATION SHEET**
**Version:** 2.0
**Date:** 04 March 2022

**Study Title: HIDDEN2: HOSPITAL DEEP VEIN THROMBOSIS DETECTION STUDY IN CANCER PATIENTS RECEIVING PALLIATIVE CARE**

## Summary

**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 time to read this sheet carefully. Please talk to others about the study if you wish.
- You may decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors.
- Ask us if there is anything that is not clear or if you would like more information.

## Important things you need to know

- Venous thromboembolism (VTE) is a disorder that includes deep vein thrombosis (DVT; a blood clot, usually in the lower leg, thigh or pelvis) and pulmonary embolism (PE; when a blood clot breaks loose and travels through the bloodstream to the lungs).
- We want to find out how many cancer patients admitted to hospital have a DVT.
- We would like to scan your upper legs for DVT using an ultrasound scanner. This will be done once at the beginning of your admission to hospital
- We would like to review this scan and other routine data collected about your condition and medications to inform our research.
- This study is sponsored and coordinated by Aneurin Bevan University Health Board and coordinated by the Centre for Trials Research (CTR) at Cardiff University.
- You can stop taking part in the study at any time.
- The study data will not identify you and will not be combined with other information in a way that could identify you.

**Contents**

**Part 1 of this document tells you the purpose of this study and what will happen to you if you take part.**



**Part 2 gives you more detailed information about the conduct of the study.**



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**This completes the summary.**

**Please ask us if there is anything that is not clear.**

**If you are considering taking part, please read the additional information in Parts 1 and 2 before making any decision and signing the HIDDEN2 Informed Consent Form.**

## Part 1

### Why is this study being done?

A previous study (HIDDen) investigated DVTs among cancer patients receiving palliative care in UK hospices. Palliative care is a medical approach aimed at improving quality of life, and minimising suffering, of patients and their families facing problems associated with life-threatening and/or complex illness. It found that 28% of patients already had DVTs but they did not cause any problems and did not need to be treated. It is thought that patients receiving palliative care admitted to hospital may have different DVT outcomes than the hospice patient group investigated in the original HIDDEN study. So we want to repeat the HIDDen study in the hospital setting in a new study, HIDDEN2. We plan to recruit 232 patients from up to four participating hospitals in South East Wales, UK.

### Why have I been invited to take part?

You have been invited to take part in the HIDDEN2 study because you are known to have cancer and have been under the care of community or hospital specialist palliative care teams.

### Do I have to take part?

No. It is up to you to decide whether or not to take part. Your nurse or doctor will answer any questions that you have. Deciding not to take part will not affect the standard of care you receive now or in the future.

If you decide to take part, your healthcare professional will ask you to sign the consent form at the end of this document to show that you have agreed to take part.

You are free to withdraw at any time, without giving a reason and with no effect on the standard of care you receive now or in the future.

### What will happen if I take part?

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

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

Before you can take part in the study a healthcare professional will collect some screening information to confirm you are eligible.

Since you meet the eligibility criteria you have been given the HIDDEN2 Participant Information Sheet (this document) and a separate Informed Consent Form. You will be given sufficient time to read a printed version of this document, to take advise from those you wish to talk to, and to decide if you wish to participate in the study.

If you decide to take part you will be asked to sign the HIDDEN2 Informed Consent Form. If you take part, your healthcare professional will assign you a unique study number that we will use to identify you. We will write this number on your Informed Consent Form.

You will then be asked brief questions about your illness and symptoms. A nurse will also examine your legs briefly.

Next you will be scanned by an ultrasound scanner (a similar machine to that used to scan people having a baby) by a specialist radiographer. . This scan will not be painful and will take approximately 20-30 minutes to scan the upper part only of both legs. It will be performed by your bedside where feasible, or in our hospital radiology department, as soon as possible after hospital admission (usually Day 1-2 following study entry).

Because we do not know whether DVT in the absence of symptoms should be treated or not with anticoagulation, the results of this study scan will not be disclosed to you or your clinical team to ensure that the study scan result does not negatively impact on your routine care. If you have symptoms and/or signs which the clinical team suspect may be due to DVT and would normally trigger a full leg scan as part of your routine care, this routine scan will be conducted following local hospital procedure in addition to the research scan. So some study participants may have a study upper leg scan and a routine full leg scan.

The answers you give, the examination and study scan result will help to determine the presence of new or changing symptoms and signs of blood clots in your body. During your participation in the study we will collect research data from your medical records and other data systems held at your local hospital site.

On average we anticipate participants to be on the study for up to six months.

## What are the possible benefits of taking part?

You will not be paid for taking part in the study and it will not alter your standard treatment in any way. However, we hope that the study results will help guide 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 in the hospital setting.

## What are the possible disadvantages and risks of taking part?

We do not anticipate that taking part will cause you any harm. There will be no cost to you for taking part. Taking part will take extra time, for example for completion of the consent form and the study scan. You will have one extra scan to those you would normally have as part of your standard care. Following your scan we will collect follow up data about you and any DVT for about 6 months. We will collect this directly from your hospital notes and/or database, so you will not need to interact with the study team after we have conducted your study scan unless you withdraw your consent.

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

Taking part is voluntary. You may withdraw your consent to take part at any time. You do not have to give a reason and will still receive the same level of medical treatment as you would in standard care. Your recruiting consultant or nurse may withdraw you from the study if considered to be in your best interest (e.g. loss of capacity or for safety reasons). If you decide to withdraw you will be asked to complete and sign a withdrawal form to specify the level of withdrawal. If you decline to complete the withdrawal form your consultant or nurse will complete it on your behalf. Anonymised study data collected before the date you withdraw will be kept and analysed. We will continue to collect follow up data from you for study purposes after the date you withdraw only if you agree to this on the withdrawal form.

**This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

## Part 2

### Who is organising and funding this study?

The Chief Investigator of this study is Professor Simon Noble, a consultant in palliative medicine at the Royal Gwent Hospital. The study will take place at up to four hospitals in South Wales, UK. Aneurin Bevan University Health Board will act as the sole sponsor and has delegated study and data management of the study to the Centre for Trials Research (CTR) at Cardiff University, Wales, UK. The study is funded by the HCRW Research for Patient and Public Benefit grant RfPPB-20-1749)P).

### Who is responsible for looking after my information?

The Sponsor will act as sole data controller for this study. Cardiff University and the participating hospitals and their governing health boards will act as data processors. All of these organisations and the CTR will be using information from you and your medical records in order to undertake this study and are responsible for looking after your information and using it properly.

### What data will we collect about you?

Relevant sections of your medical notes will be looked at. Some of this **special data** will be collected **indirectly** by your healthcare professional from previously collected data or your future medical records or database(s), for example:

- Historical data to determine your eligibility to take part
- Data about your VTE standard care and treatment
- If you were to die whilst taking part, we would collect the date you died and whether or not the cause was due to thromboembolism.

The following **personal data** will also be collected **indirectly** by your healthcare professional from previously collected medical records or database(s):

- Year of birth
- Biological sex
- Ethnicity

Your rights to access, change or move the data we collect are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep data about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable data possible.

## What will happen with the personal and special data I provide?

Your hospital will securely transfer any personal and special data collected about you for the study to the CTR at Cardiff University where it will be securely stored for a minimum of 5 years for regulatory archiving purposes, and indefinitely under the legal basis of 'task in the public interest' and 'legitimate interest' in line with Cardiff University and Sponsor policies, UK research ethics, and UK GDPR.

Your hospital will use your name, NHS number and contact details to contact you about the study, and ensure that relevant information about the study is recorded for your care. Your NHS number and contact details will **not** be transferred to other organisations.

Your unique HIDDEN study number and year of birth will be used by the hospital and the CTR alongside your year of birth to identify you on the study-specific database(s) and data forms.

A copy of your consent, and any subsequent withdrawal, form(s) (including your name and initials) will be securely sent to and stored at the CTR for the purpose of monitoring consent and withdrawal only.

We will use your age, biological sex and ethnicity to determine if there are differences in VTE outcomes for these different patient groups.

Individuals from the Sponsor, the CTR and regulatory organisations may look at your medical and research records to check the accuracy of the study.

## Will my information be kept confidential?

Yes. We will follow ethical and legal procedures. All information collected about you and your standard care during the study will be confidential and bound by the terms of the UK General Data Protection Regulation (GDPR) and UK Data Protection Act (DPA) 2018 and subsequent amendments. All members of the study team and regulatory authorities are trained in data protection. People who do not need to know who you are will not be able to see your personal data.

By signing the consent form, you only allow people working on the study, or to ensure the study is being run correctly (for example auditors), to have access to your data. Other people who analyse the information will not be able to identify you or access your personal data. Records identifying you will be kept confidential and will never be made publicly available. If the results of the trial are published, your identity will remain confidential.

With your permission your General Practioner will be notified that you are taking part in the study. A separate box on the consent form will ask your consent for this.

You can find out more about how we use your information at:

Sponsor Website: https://abuhb.nhs.wales/about-us/information-governance/

Telephone: 01495 765019 or 01495 765085
Email: infogov.abb@wales.nhs.uk

If you have a concern about any aspect of this study, please contact the Sponsor at ABB.RandD@wales.nhs.uk, or Cardiff University at inforequest@cardiff.ac.uk

If you remain unhappy and wish to complain formally, you can contact the Information Commissioner's Office (ICO) telephone helpline on 0303 123 1113 or https://ico.org.uk/global/contact-us/live-chat/

## What data is intended to or likely to be used for future research?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations for future research. These organisations may be universities, NHS organisations or companies involved in health and care research in the UK or European Economic Area. Your information will be used in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. It will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

## What information about me will be published by the Sponsor/CTR/Cardiff University?

As a university, Cardiff University uses personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

## What will happen to the results of the study?

The results may be shown at medical meetings and submitted to research journals for publication. You will not be identified in any way in any study report or publication. A lay summary of the study results will be sent to the participating hospital and, where possible, forwarded to participating patients. The results of the study, and where possible publications, will be made publicly available on the CTR website (https://www.cardiff.ac.uk/centre-for-trials-research) and other suitable organisation websites, for example Cancer Research UK (https://www.cancerresearchuk.org/) and/or relevant publicly accessible research databases.

## Who has reviewed this study?

This study has been approved by Wales Research Ethics Committee 4 and received independent peer review by the funders and a statistician.

## How have patients and the public been involved in this study?

We have recruited two research partners from the public to support the development and conduct of this study and to review the information sheet and consent form.

## What happens if something goes wrong?

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Sponsor, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will also be available to you.

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. In the event that something goes wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for legal action against the organisations involved including the Sponsor or the National Health Service (NHS). However, you may have to pay your legal costs. The NHS complaints mechanisms will still be available to you (if appropriate). Details can be obtained from your hospital.

If you have a concern about any aspect of this study, please speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can contact [insert details e.g. NHS Complaints Procedure]. Details can be obtained from [insert details].

## What if new information becomes available?

Sometimes during a research study new information becomes available about the condition being studied. If this happens, your hospital doctor will discuss this with you and whether or not you want to take part. Your doctor might consider it to be in your best interests to withdraw from the study. If you decide to continue taking part you may be asked to sign an updated consent form.

## Further information and contact details:

If you have any further questions concerning this study, please contact your hospital **Healthcare Professional:**

**Name: …….**

**Title: ……**

**Tel: ……..**

**This completes Part 2**

**THANK YOU FOR CONSIDERING TAKING PART IN THIS STUDY.**

**If you are interested in taking part in the study, please read and complete the HIDDEN2 Informed Consent Form.**