Contact: 01865 231409
Prof Peter Watkinson

PARTICIPANT INFORMATION SHEET FOR THE SHINE STUDY
Screening for Hypertension in the INpatient Environment: (SHINE): A Diagnostic Accuracy Cohort Study

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask to discuss the study with a member of the research team.

What is the purpose of the study?

The aim of this study is to create guidelines for detecting and treating patients with undiagnosed high blood pressure. Our research has found that lots of patients admitted to hospital with other problems may also have high blood pressure and not know about it. We want to improve blood pressure control in the UK by creating some guidelines for patients and their health care providers about what to do when a patient has raised blood pressure during a hospital stay.

We have created a way to distinguish patients that might have high blood pressure from those who don't. To make this system accurate and reliable, we need to test it and refine it with the help of patients. We believe the right way to do this is to test your blood pressure after you have left hospital and get your feedback on the system.

What is high blood pressure and how is it measured?

High blood pressure (also known as hypertension) is when the pressure of blood flowing through your arteries is higher than it should be. This makes the heart work harder to pump blood through the vessels around your body. High blood pressure can cause serious long-term health problems and is very common, with 1 in 4 people in the UK affected. Blood pressure is measured using a device called a blood pressure cuff or monitor. This measures how high the pressure of blood is flowing through one of the arteries in your arm. The measurement can be done in hospital, at your GP surgery or at home.

Usually hypertension is diagnosed using blood pressure measurements taken at home. This is because people's blood pressure may be higher when they're in the hospital or GP surgery. The most reliable way to test blood pressure at home is to wear a blood pressure monitor for 24 hours. The monitor automatically takes readings

over 24 hours and stores them in the device. A nurse or doctor then downloads the readings and looks at the results.

Why have I been invited?

We are inviting people to take part who have been in hospital for more than 24 hours and who have had several blood pressure measurements taken during this time. To make sure the system can appropriately distinguish people with high blood pressure from people with normal blood pressure, we need to recruit a variety of patients with different hospital blood pressure measurements, including people who we think have normal blood pressure. To check whether the system works, we would like to measure your blood pressure when you're at home to see if your blood pressure readings at home match with your readings in hospital. There isn't currently a definition of high blood pressure in hospital, but please speak to the researcher who gave you this leaflet if you would like to discuss your blood pressure

We would like around 200 patients who have had regular blood pressure readings during their hospital stay, to take part in the study and complete a 24 hour blood pressure test.

Do I have to take part?

No, whether you take part or not is entirely up to you. If you do decide to take part you can change your mind at any time without giving a reason. Withdrawal from the study will not affect the care you receive.

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

If you decide to take part in the study, a member of the research team will answer any questions you have before asking you to read and sign the consent form. If you are still in hospital, a member of the research team will take a blood pressure reading from you. You will also be asked some questions about your health and medical history that may be relevant to your blood pressure. You will be asked to have a 24-hour blood pressure test once you have left hospital and are at home. The study team will arrange this with you for between 4 and 26 weeks after you have returned home from hospital. The research team will pay for your travel if you need to attend appointments at a clinic for your blood pressure monitor fitting and removal. If you are unable to travel, you may be offered a visit where a member of the research will come to your home, workplace or other appropriate location, or, if it is not appropriate to see you in person (e.g. due to COVID-19 restrictions), you may have the monitor delivered to your home and you will be guided through how to put the monitor on by phone or video call.

Whilst wearing the 24-hour blood pressure monitor you can carry out your everyday activities but as the monitor is not waterproof, we ask that you don't shower or bathe for this period. The monitor should be switched off whilst driving a car. You will be shown how to turn the monitor off and back on. The research team will help you fit the monitor (either in person or by talking you through it), explain how it is worn and then advise you how to remove and return it after the 24-hour recording (this may be at a second appointment or you may be instructed to remove the monitor yourself). Before being fitted with the monitor we will check that you have a regular pulse rate. If we

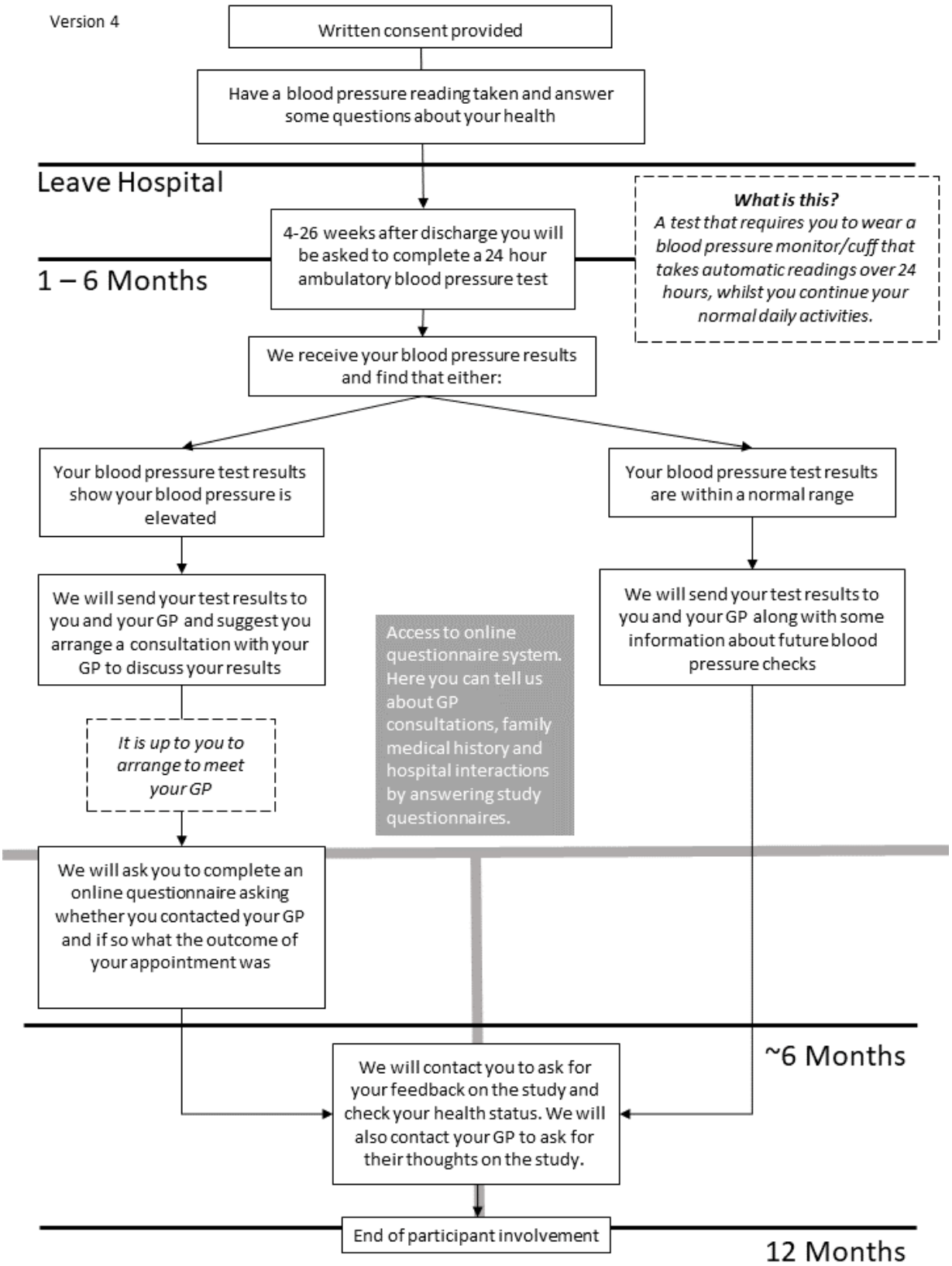
detect that your pulse rate is irregular, we may not be able to proceed with blood pressure monitoring. If this occurs we will write to your GP to let them know what we have found. To be able to calculate your average blood pressure over 24 hours, the monitor needs to have collected enough blood pressure recordings. If there aren't enough recordings and you are willing, we will ask you to have a further 24 hour period of blood pressure monitoring. In the rare event of us not having enough readings on the second occasion, and if your blood pressure was elevated during your time in hospital, we will write to yourself and your GP to ask you to arrange a consultation together to review your blood pressure in the surgery.

We will use the recordings from the monitor to understand your blood pressure. We will write to you and your GP with the result within four weeks of you returning the monitor. We will also write to you and your GP with a recommendation based on your results. If your blood pressure is high, we will recommend you make an appointment with your GP. If your blood pressure is within a normal range we will provide you with some information about future blood pressure checks. If we find that your blood pressure is very high, we will inform you the same day and telephone your GP the same day also.

After your 24 hour blood pressure monitoring you will be sent an access link to an electronic questionnaire system. We would like you to use this to record information about any GP consultations you have where you discuss your blood pressure. You will also be able to record any blood pressure readings that have been taken by yourself, your GP or practice nurse since you joined the study.

You will be asked to complete a feedback questionnaire about six months after joining the study. The questionnaire will ask you about how you found having your blood pressure monitored and the information we sent you during the study. The feedback questionnaire will be available on the electronic questionnaire system or can be posted to you if you would prefer to complete this on paper. If we do not receive your questionnaire response within 4 weeks, a study team member may contact you to remind you. You will be able to provide feedback for up to 1 year after joining the study. If during this time, you provide us with feedback that would benefit from discussion with a researcher, we may contact you to discuss things further.

After twelve months your involvement in the study will end.


Version 4
Written consent provided
Have a blood pressure reading taken and answer some questions about your health
Leave Hospital
1 – 6 Months
4-26 weeks after discharge you will be asked to complete a 24 hour ambulatory blood pressure test
What is this?
A test that requires you to wear a blood pressure monitor/cuff that takes automatic readings over 24 hours, whilst you continue your normal daily activities.
We receive your blood pressure results and find that either:
Your blood pressure test results show your blood pressure is elevated
Your blood pressure test results are within a normal range
We will send your test results to you and your GP and suggest you arrange a consultation with your GP to discuss your results
We will send your test results to you and your GP along with some information about future blood pressure checks
Access to online questionnaire system. Here you can tell us about GP consultations, family medical history and hospital interactions by answering study questionnaires.
It is up to you to arrange to meet your GP
We will ask you to complete an online questionnaire asking whether you contacted your GP and if so what the outcome of your appointment was
~6 Months
We will contact you to ask for your feedback on the study and check your health status. We will also contact your GP to ask for their thoughts on the study.
End of participant involvement
12 Months

What should I consider?

You may be able to take part in this study even if you have other medical conditions. You should continue to take your usual medication whilst taking part in this study. You may be able to take part in this study whilst taking part in other research studies.

You CANNOT take part in this study if:

- you are currently taking medication for high blood pressure (it is fine for you to begin taking medication during the study, after you have completed the 24 hour blood pressure monitoring)
- if you are pregnant, trying to become pregnant or have been pregnant in the last three months
- if you have been diagnosed with atrial fibrillation (AF)
- if you are receiving chemotherapy or are due to start chemotherapy
- if you are being moved to another hospital or treatment facility
- if the reason for you being in hospital at the moment is a heart attack, stroke, haemorrhage (internal bleeding) or health problems due to very high blood pressure.

If you have any questions please discuss these with the person who has given you this leaflet or contact the research team using the information at the end of this leaflet.

Are there any possible disadvantages or risks from taking part?

Blood pressure monitoring is a simple and common medical test. Because of this we do not expect any serious risks to occur from your participation. Some people find having their blood pressure taken uncomfortable but there are no medical risks involved. Completing the baseline and follow-up questionnaires will take up to 15 minutes of your time.

What are the possible benefits of taking part?

It is possible that during the course of this study we might detect that you have high blood pressure that needs treatment. If so, we will contact you and your GP to recommend you have an appointment together to discuss this. Untreated high blood pressure can have long term effects on your health. Picking it up as part of the study, might benefit your health. Some people who take part in this study will not have high blood pressure and therefore may not directly benefit from taking part in this study. These people will be helping research and may improve their knowledge and understanding of high blood pressure.

Will my General Practitioner/family doctor (GP) be informed of my participation?

We will tell your GP that you are taking part in this research. Unfortunately, if you do not want us to inform your GP, you cannot take part in this research. This is because we have a duty to inform your GP if the study finds that your ambulatory blood pressure is high. Your GP will receive relevant results from your time in hospital. This will include some of the blood tests taken routinely in hospital, any heart traces

(electrocardiograms) which may have been performed in hospital and your average blood pressure in hospital. Once you have had the 24 hour blood pressure monitoring, we will write to you and your GP with the results. At the end of the study, we will ask your GP for their feedback on the letters we sent them. We will also ask if they found the information we gathered helpful in providing you with blood pressure care.

Whether you choose to take part in this research or not will not affect your ongoing care from either your GP or the hospital.

Will my taking part in the study be kept confidential?

Personal identifiable data (e.g. your name, date of birth, NHS number) will be collected so we can contact you. This will be to perform study procedures like asking you to complete questionnaires and arranging your 24 hour blood pressure test. These data will be stored on a secure, encrypted database, separate from your data collected for research purposes.

Information collected for research purposes (e.g. answers to questionnaires, blood pressure readings) will only be identified using a unique patient study code. Data will be stored on University of Oxford or NHS computers accessible only by members of the research team.

ECG reports taken using an AliveCor device will be stored on AliveCor EU Data Privacy compliant servers. ECGs will be anonymous and none of your identifiable data will supplied to AliveCor.

Responsible members of the University of Oxford and the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with necessary regulations.

We are interested to know how your health is in the longer term. The research team will therefore contact NHS Digital in 10 years' time to enquire as to whether you have had any major health problems. After this point, any personal data will be destroyed.

What will happen to my data?

We will be using information from you, your medical records, your GP and blood pressure monitoring tests in order to complete this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you, such as your contact details, for 10 years after the study has finished. Research documents with de-identified information will be held securely at the University of Oxford for 20 years after the end of the study.

The research team at the relevant NHS Trust will collect information from you and your medical records for this research study in accordance with our instructions. They will use your contact details, GP details, and medical records to allow us to contact you

and your GP with information about your blood pressure and document relevant study information from your medical records. A copy of the consent form will be included in your medical notes and retained in keeping with the NHS Trust medical notes retention policy.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting shine.study@phc.ox.ac.uk

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

Participation in this research is voluntary. If you change your mind and withdraw from the study, this will not affect the care you receive from the NHS or your GP. If you withdraw from the study, unless you state otherwise, any data which has been collected whilst you have been in the study will be used for research as detailed in this participant information leaflet. You are free to request that your data are destroyed at any time during the study. After the study has finished, personal identifiers will be destroyed. This means we will be unable to identify your research data record to destroy it after this point.

What will happen to the results of this study?

No participant will be identifiable from any report or publication placed in the public domain. We intend to publish the findings of this study in an academic journal. All papers will be open source and available to the public. Results will also be presented at appropriate conferences. A summary of the findings will be made available on the department website, which is accessible to the public.

What if there is a problem?

Given the nature of this study, it is highly unlikely that you would suffer harm by taking part. However, the University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment provided by your GP and during your time in hospital.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Peter Watkinson by phone: 01865 572609 or email: peter.watkinson@ndcn.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 (6)16480, or the head of CTRG, email: ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the

care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team, please email or phone .

Who is organising and funding the study?

This research is a collaboration between researchers, doctors and engineers at Oxford University Hospitals NHS Foundation Trust and the University of Oxford. This research is funded by the NIHR Oxford Biomedical Research Centre for the Technology and Digital Health theme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central - Oxford B Research Ethics Committee.

Further information and contact details:

If you would like any further information regarding this study, please contact the research team using the details below:

Research Team:

Oxford: 01865 231409

Warwick: 01926 495321 Ext 8645

Dr Laura Armitage: laura.armitage@phc.ox.ac.uk or 01865 289340

Thank you for considering taking part.