**Impact of daily blood pressure patterns on detecting hypertension**

**PARTICIPANT INFORMATION SHEET**

Central University Research Ethics Committee Approval Reference: R77097/RE001

## Introductory paragraph

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

## Why is this research being conducted?

Blood pressure measured by an inflatable cuff in a clinic is often used to screen for high blood pressure (hypertension), a condition associated with long term heart problems. However, measuring blood pressure in a clinic like this doesn’t fully account for the fact that your blood pressure varies naturally throughout the day. This means that some patients with high blood pressure may be missed.

Blood pressure has a known daily (circadian) pattern, which normally involves a dip overnight and an increase during the day. However, some people experience the opposite, with elevated blood pressure at night and lower levels during the day. This is known as nocturnal hypertension and is associated with a significant increase in long term risk of heart problems. Further, as blood pressure is elevated at night, rather than during the day, in these patients, they are at a high risk of being missed by the traditional screening process for high blood pressure.

We are investigating the use of a wrist-worn blood pressure monitoring device (Aktiia) to establish an individual’s daily blood pressure profile. This device doesn’t use a cuff, but instead uses optical sensors to non-disruptively estimate blood pressure. If this device is able to accurately capture an individual’s daily blood pressure profile, it would allow us to detect patients with nocturnal hypertension relatively easily and without too much disruption to the patient. This, in turn, would allow for medication to be prescribed to these patients, improving their long-term health.

## Why have I been invited to take part?

You have been invited to take part as you are a healthy adult aged between 21 – 65 years, and have expressed an interest in taking part in the study. Overall, we intend to recruit 10 – 20 participants, mostly friends, family, and colleagues of the research team. You will not be able to participate in this study if you suffer from a heart rhythm disorder (like tachycardia or arial fibrillation), diabetes, kidney dysfunction, or are pregnant.

## Do I have to take part?

No. It is up to you to decide whether or not to take part. You can withdraw yourself from the study, without giving a reason, by advising us of this decision. Should choose to withdraw, all information gathered during the study pertaining to you will be deleted.

## What will happen to me if I take part in the research?

If you take part in the research, you will make two visits to the Institute of Biomedical Engineering, and wear a monitoring device for a week between the two visits:

**Visit 1:** This visit will last approximately 30 minutes. We will discuss this information sheet, answer any questions you may have, and take informed consent.

You will then be provided with an Aktiia device. This is a wrist-worn blood pressure monitoring device. You will be asked to install the Aktiia app on your smart phone (or provided with a smart phone for the duration of the study, if preferred) and guided through pairing the Aktiia device with your smart phone and setting up the device using an Aktiia provided blood pressure cuff. You will also be instructed on the process of viewing your blood pressure measurements in the app. You may ask to pause or stop this process at any time.

After this process, you will be asked to wear the device on their wrist for a week (including overnight) apart from when showering, bathing, or swimming. You will be asked to either enter blood pressure measurements daily into a Nexus365 OneDrive for Business spreadsheet provided directly and specifically to you, or have measurements entered by the research team at the end of the week’s home monitoring.

**Visit 2:** This visit will last approximately 10 minutes. After one week, you will return to the Institute of Biomedical Engineering and the device will be unpaired and data deleted from your smart phone.

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

There are no foreseeable disadvantages or risks to taking part in the study. You will be asked to wear a wrist-worn device for a week, and avoid immersing it in water (the device is splash proof), but otherwise to act as normal. You will not be identifiable from any data that may be published from the study.

## Are there any benefits in taking part?

If you appear to have hypertension as assessed by day-time and/or night-time average blood pressure measurements from the Aktiia device, according to the standard criteria defined by the National Institute for Clinical Excellence (NICE), you will be advised to inform your GP and arrange to be screened.

## What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We will collect some basic demographic information (age and gender) as well as blood pressure measurements provided by the wrist worn Aktiia device. Your data will be deidentified, with your name replaced by a participant number. Data will be stored on a secure, password protected server at the Institute of Biomedical Engineering for three years after publication of the results of the study, after which it will be deleted. Consent forms will be stored in a locked filing cabinet at the Institute of Biomedical Engineering and will also be destroyed three years after publication of the results of the study.

The research team will have access to the research data.

We would like your permission to use this data in future studies. Participants will not be identifiable from this data, which will only contain a participant number, age, gender, and blood pressure measurements.

## Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will/may be written up in academic publications. No participants will be identifiable in the final publications.

## Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from <https://compliance.admin.ox.ac.uk/individual-rights>.

## Who is funding the research?

This study is being funded by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC).

## Who has reviewed this study?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: R77097/RE001).

## Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this study, please contact Dr. Shaun Davidson (e-mail: shaun.davidson@eng.ox.ac.uk) or Prof. Lionel Tarassenko (e-mail: lionel.tarassenko@eng.ox.ac.uk), and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

The Chair, Medical Sciences Interdivisional Research Ethics Committee;
Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

## Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Doctor Shaun Davidson
Institute of Biomedical Engineering
Old Road Campus Research Building, Roosevelt Drive, Oxford OX3 7DQ
Tel: 01865 617722
E-mail: shaun.davidson@eng.ox.ac.uk