

## **Research Participant Information Sheet**

28<sup>th</sup> October 2011 (Version 1)

### **Easy and Accurate Manual Blood Pressure Measurement**

*You are being invited to take part in a research study. 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 or not you wish to take part. Your participation is entirely voluntary and you may withdraw your consent at any time and do not have to justify your decision.*

#### **What is the purpose of the study?**

This investigation will research ways of recording blood pressure more easily and accurately.

#### **Why have I been chosen?**

Anyone over 18 years old is eligible to take part in this study.

#### **Do I have to take part?**

No. Your participation in this study is completely voluntary. If you do decide to take part you will be given this information sheet to keep together with a copy of the signed consent form. You are under no obligation to participate in this study, and you may withdraw at any time without it affecting your normal care in any way.

### **What will be involved if I agree to take part in the study?**

If you agree to take part in the study, we will ask you to sign a consent form after reading this information sheet. The following measurements will be made:

- **Systolic and diastolic blood pressure** will be measured manually using a standard blood pressure monitor.
- **ECG** – your heart rate will be recorded by placing three ECG electrodes on your chest, one near your right shoulder and two at the left side.
- **Respiration** will be recorded using a sensor on the chest.
- **Blood flow sounds** will be recorded near the elbow.
- **Arm movement** will be recorded by a small sensor on the arm.

Blood pressure measurement will be repeated three times using different sensors to measure blood flow sounds. The whole session should take about 40 minutes of your time. The data will be recorded to a computer and analysed. No measurement is invasive or involves needles. All measurements are in regular clinical use and are safe.

### **What are the benefits?**

There are no benefits to you personally by taking part in this study, but the results should eventually benefit others, giving information for clinical diagnosis, therapy assessment and detecting cardiovascular disease early.

### **What are the risks?**

There are no risks in taking part in this study.

### **What if some unknown clinical condition is discovered?**

A consultant relevant to the finding will be contacted, and if an abnormal condition is confirmed your GP will be informed, and if appropriate you will also be contacted by the hospital consultant.

### **Will my taking part in this study be kept confidential?**

Your data will be anonymised and identified by a code. All information will be kept strictly confidential. The combined results from all subjects will be analysed and may be published.

**What happens if something goes wrong?**

If you are harmed as a result of taking part in this study, then compensation can be sought from the study sponsor under the NHS Indemnity arrangements. A copy of the guidelines is available on request.

However, the sponsor will not compensate you where harm results from any procedure that is not in accordance with the study protocol. Under these circumstances, your right at law to claim compensation for harm where you can prove negligence is not affected.

**What will happen to the results of this study?**

The results of this research will be disseminated by presentations at scientific meetings and published in peer review journals. We will publish the references on our website

<http://www.rmpd.org.uk/publications.htm>. Individual data will not be identifiable in any paper or report.

**Who is funding the research?**

This work is funded by Engineering and Physical Sciences Research Council (EPSRC).

**Who has reviewed the research?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by a local Research Ethics Committee.

**Further information**

If you have any questions or would like further information please contact:

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If you would like to seek independent advice about participating in the study please contact:

Patient Advice and Liaison Service

Telephone: 08000 320202

Email: [northoftynepals@nhct.nhs.uk](mailto:northoftynepals@nhct.nhs.uk)

Thank you for your interest in our work and for reading this sheet.