NON-INVASIVE MEASUREMENT OF BLOOD PRESSURE

Blood pressure is a vital sign that is routinely checked in many clinical situations, and assesses the pressure of blood as it flows through arteries from the heart to the body. Devices to check blood pressure can be purchased by the general public for use at home. Non-invasive blood pressure monitoring typically includes measurement of the systolic (maximum) and diastolic (minimum) pressures, although other pressures such as the mean arterial pressure (MAP) and pulse pressure may be used.

Blood pressure measurement is recognised as a safe, non-invasive test, carried out in numerous clinical and non-clinical environments. This guidance addresses the ethical issues involved in making measurements of blood pressure in the arm using methods that do not go beyond contact with the outer body surface.

Measurement of blood pressure involves the placement of an inflatable cuff around the arm, typically just above the elbow. This is then inflated to a pressure above the systolic pressure, and slowly deflated while the measurements are made. Each measurement should take about a minute. Use of a manual sphygmomanometer usually also involves the placement of a stethoscope just below the cuff, so that the researcher can hear the blood flowing through the artery, and identify the sounds that are used to define systolic and diastolic pressure.

Other less familiar methods require a cuff on a finger, which detects the volume and force of blood entering the finger with each heart beat (pulse volume plethysmography - PVP). There is little or no discomfort and no inflation to occlude blood flow. The cuff can remain on the finger during the research. PVP can also be used on other areas, such as the lower limbs, to measure blood flow – these procedures are outside the remit of this guidance.

If multiple measurements are to be made close together in time (for example, to obtain an “average” blood pressure, or for assessments of equipment accuracy), there should be a break of at least 30 seconds between consecutive measurements, and the number of measurements made on each arm be limited to a maximum of 7.

If the participant experiences skin changes, including bruising or chafing, excessive discomfort, or any other adverse symptoms, the testing procedure should be terminated.

**Communication of results**

It is likely that participants will be interested in their measured blood pressure, and some may have pre-existing concerns about this. It is important that participants are advised that measurements made in the study context are not diagnostic, and that they should contact their own doctor if they have any concerns. Measurements made during studies may be affected by anxiety, sometimes called “white coat” effects, which will tend to increase the measured blood pressure, and may also be affected by other study interventions.
As participants are likely to be interested in their own blood pressure, it is appropriate for them to be provided with a written record of their blood pressure recorded during the study. This will be the baseline or mean value if multiple measures are made.

It is possible that measurement of blood pressure during a study may identify participants with undiagnosed hypertension (high blood pressure), and it is appropriate for this information to be communicated to the participant and their medical team. If the blood pressure value provided to the participant is higher than the international standard for the definition of hypertension (140mmHg systolic, or 90mmHg diastolic), and the participant is not aware of an existing diagnosis of hypertension, participants should be advised to get a repeat reading, for example at a pharmacy or GP practice and, if still elevated above 140/90, discuss their blood pressure with their general practitioner. If the blood pressure measured is above 180/120, the reading should be repeated, and if still above 180/120, participants should be advised to seek urgent assessment by their GP (within 7 days, or sooner if they feel unwell) or via the NHS 111 service (if they cannot get a GP appointment).

The researcher should explain that blood pressure is variable, and that a high reading on one occasion does not necessarily indicate the presence of disease or increased risk. The Appendix provides an example document that could be provided to the participant.

Further Information

NHS guidance - https://www.nhs.uk/common-health-questions/lifestyle/what-is-blood-pressure/
Your measured blood pressure: _____ / _____

Date: __________________

**Blood Pressure**

Thank you for taking part in our research study.

*Why have I been given this information sheet?*

We have given you this information sheet because the blood pressure we measured today may indicate high blood pressure (more than 140/90).

*What is high blood pressure?*

High blood pressure means that your blood is being pumped around your body at a higher pressure than would be expected. High blood pressure can increase your chance of developing conditions such as heart disease, or a stroke. Treatment usually includes losing weight if you are overweight, regular physical activity, a healthy diet, cutting back on alcohol, and stopping smoking. Many people also need medications to lower their blood pressure.

*Do I have high blood pressure?*

Not necessarily. A one-off measure of blood pressure does not mean that you have high blood pressure. Your blood pressure goes up and down throughout the day, and can sometimes be higher than usual if you are feeling nervous or stressed. Your blood pressure that has been measured today is higher than would be expected, but this needs to be checked several times to make sure it is truly high. It may normally be higher or lower than this level.

*What should I do now?*

You should contact your GP practice, so that they know that your blood pressure today was high. Your GP practice may decide to do more tests or measurements of blood pressure if they think that you may have high blood pressure.

*Information for the GP*

The blood pressure indicated is the average (mean) of ____ blood pressure measurements made using a calibrated blood pressure monitor. These measurements were made as part of a research study investigating [insert relevant information to study]. All measurements were made in accordance with standard protocols. The patient may already have a diagnosis of hypertension, and you may already know about their blood pressure control.

For further information on this study, please contact **Researcher Name on 01865 xxxxxxx or email researcher.name@dept.ox.ac.uk**