



**Note: This Approved Procedure can be combined with Approved Procedure CUREC\_AP\_IDREC\_18 "Studies using Psychophysiological Methods with Adults"**

## **STUDIES INVOLVING THE NON-INVASIVE MEASUREMENT OF BLOOD PRESSURE IN THE ARM**

### **1. SCOPE**

Blood pressure is a vital sign that is used in many clinical situations, and assesses the pressure of blood as it flows through arteries from the heart to the body. This Approved Procedure is relevant to studies where blood pressure is measured in the arm, either using an automated sphygmomanometer, or a manual sphygmomanometer and stethoscope. Blood pressure monitoring is technically an 'invasive procedure (Class B)', defined in the [CUREC glossary](#) as a procedure involving the 'passive recording of function by contact with the outer body surface'. This Approved Procedure only 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, referred to in this Approved Procedure as non-invasive measurement of blood pressure. Studies that also involve other Class B invasive procedures, or raise other ethical issues (e.g. by the inclusion of children, or the use of deception) may require independent ethical scrutiny or reference to other Approved Procedures or guidelines.

Non-invasive blood pressure monitoring typically includes the 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. The procedure can also be used to measure the heart rate, particularly if an automated sphygmomanometer is used.

Non-invasive measurement of blood pressure involves the placement of an inflatable cuff around the arm, typically just above the elbow or at the wrist. This is then inflated to a pressure above the systolic pressure, and then 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.

As non-invasive measurement of blood pressure is commonly carried out in clinical situations, many participants will be familiar with the procedure, and will have experienced it before. Despite this, the procedure will be fully explained before it is carried out.

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). There is little or no discomfort and no inflation to occlude blood flow. The cuff can remain on the finger during the research.

### **2. TRAINING OF RESEARCH STAFF**

Training should be provided for the type of sphygmomanometer used in the study. Training in the measurement of blood pressure using a manual sphygmomanometer will be carried out by a qualified health care professional familiar with the procedure. Training in the use of an automated sphygmomanometer will be provided by an experienced researcher or qualified health care professional, and will be in accordance with the manufacturer's instructions.

### **3. METHODS FOR RECRUITING PARTICIPANTS**

Participants for blood pressure studies are typically recruited via posters or emails within the University (see example poster associated with this Approved Procedure).

### **4. INFORMATION PROVIDED TO PARTICIPANTS**

The specific details provided will vary depending on the study, but will always be on University headed paper, showing the department name and address.

The Information Sheet must be written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults.

The information sheet will also explain that the study carries no significant personal risk and that the data will be anonymised.

In addition, a verbal explanation will be given to all participants by the researcher conducting the study.

Please refer to the **Information Sheet associated with this Approved Procedure.**

### **5. CONSENT OF PARTICIPANTS**

Written informed consent must be obtained from all participants using the Consent Form associated with this Approved Procedure. Consent will be obtained for each study by a researcher trained in taking informed consent.

Participants will sign, print and date their names and the researchers who secure the consent will also sign, print and date their names.

Please refer to the **Consent Form associated with this Approved Procedure.**

Current guidance on the informed consent process can be found on [the University's Research Ethics webpage on consent](#).

### **6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS**

Participants may be reimbursed for any reasonable expenses incurred (e.g. travel).

### **7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE**

Blood pressure measurement is recognised as a safe, non-invasive test, carried out in numerous clinical and non-clinical environments. There is a small risk of discomfort or bruising to the upper arm due to the inflation pressures of the cuff - this is minimised by choice of an appropriate cuff size. As some people feel faint during or after a blood pressure measurement, a first aider or medical professional will be available during testing, and the researcher will be trained in the recognition and initial treatment of fainting.

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 will be a break of at least 30 seconds between consecutive measurements, and the number of measurements made on each arm will 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 will be terminated. To ensure hygiene, hands will be washed between participants.

## **8. MONITORING AND REPORTING OF ADVERSE OR UNFORESEEN EVENTS**

If a subject becomes unwell, or is injured during a test session, the session will be terminated. Trained staff will provide appropriate first aid, and the incident reported in the appropriate Accident Book.

Adverse events will be reported promptly to the principal investigator, who will determine what, if any, measures need to be taken to reduce the risk of future events.

## **9. 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 “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 during the study (see attached sheet). This will be the baseline or mean value if multiple measures are made, and will be calculated from values measured with the most accurate device if multiple devices are used.

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 international standard for the definition of hypertension (140mmHg systolic, or 90mmHg diastolic), and the participant is not aware of an existing diagnosis of hypertension, an information sheet (see example attached) will be provided, and the participant will be advised to discuss their blood pressure with their general practitioner. The researcher will 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.

If the study involves children, appropriate clinical values will be used to define participants who require further investigation from their own doctor.

## **10. DUTY OF CARE ISSUES / CONFIDENTIALITY**

Participants with a blood pressure of greater than or equal to 140/90mmHg (as defined in section 10) may have clinical hypertension, which increases the risk of heart disease, stroke, and other serious conditions. Hypertension can be treated with medication, resulting in lowered risk of these cardiovascular diseases. Patients with a blood pressure of greater than or equal to 140/90mmHg will be issued with a written advice sheet with their systolic and diastolic blood pressures recorded on it, and advised to seek the advice of their own doctor.

## **11. DATA PROTECTION ISSUES**

Each participant is given a code number, and this, rather than the name, is used to label all data from the study, including computerised files and any paper records. If it is necessary to retain any personal

information (e.g. contact details in the case that participants may be re-tested or for late withdrawal of consent) the key linking codes to personal details will be kept in a locked filing cabinet.

Names and contact details of participants who wish to be informed of the results of the research will be stored separately from the research data, and will not be associated with the participants' study identifier.

Research data will be stored for a period of 10 years in accordance with guidelines imposed by major funding bodies. At the end of this time it will be destroyed.

Personal data will be destroyed as soon as it is no longer required for the study.

## 12. FURTHER INFORMATION

The following sample documents are available: consent form, participant information, hypertension information, poster and notification slips.

## 13. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
1.0	Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
1.1	Updated hyperlinks for new CUREC website	1.0
2.0	Addition of text to section 1 about pulse volume plethysmography. Removal of specific list of information to be provided from section 4, and list of consent form contents from section 5.	1.1
2.1	Text to indicate procedure may be combined with AP18	2.0
2.2	Removed reference to sections of the old CUREC 1 checklist	2.1
2.3	Updated to improve accessibility	2.2