

PARENT INFORMATION SHEET

Office and Ambulatory Blood Pressure Norms in Singapore Children

1. BACKGROUND

High blood pressure (hypertension) is a serious problem in adults. High blood pressure is also known as the “silent killer” in adults as the person with high blood pressure usually does not feel sick. The only way to diagnose high blood pressure is for a doctor to measure the blood pressure.

High blood pressure does not only affect adults. Some children also have high blood pressure due to a variety of medical reasons. In order to diagnose high blood pressure in children, we need to know what the normal blood pressure of healthy children is. This will help doctors to identify when a child’s blood pressure is too high so that they can help the child.

2. PURPOSE OF THE STUDY

This is a research study in which we are interested in taking the blood pressure of children from 6 years old to 16 years old in order to obtain the range of normal blood pressure in our local healthy children. This will be done in the same way that blood pressure is checked in the doctor’s office using a mercury sphygmomanometer. This is known as “office blood pressure”. We are hoping to involve a total of 5000 children aged 6-16 years old over a period of 2 years.

We are also carrying out a separate check of blood pressure using a new device called an ambulatory blood pressure (ABP) monitor.

In adults, this way of measuring blood pressure is found to be more accurate than the office blood pressure readings, as it measures blood pressure much more frequently throughout the day, giving the doctor a better understanding of how the blood pressure varies or changes during daily activities.

Doctors treating children with high blood pressure are using this ABP monitor more often as it may be more accurate than the office blood pressure measurement. Similarly, we need to know what the ABP readings in normal healthy children are before we can diagnose an abnormal ABP reading. We are hoping to recruit 1800 children in this part of the study.

3. STUDY PROCEDURE

Our team will go to your child’s school during school hours. With your consent, we will record your child’s height, weight and blood pressure (also called ‘office blood pressure’) of your child during one of the sessions in school. This involves 2 measurements of blood pressure. If the blood pressure is found to be abnormally high, we will inform you and advise on the followup necessary.

If you give your consent for the ABP part of the trial, we will teach your child (if he/she is old enough to understand) how to use the ABP monitor (Spacelab 90217 model). For the younger children in primary school, we will arrange to meet up with you or the caregiver at a time and place convenient to you to teach you how to use the machine. This machine is routinely used to monitor blood pressure on adults and children with high blood pressure. It is widely used in Europe and the United States and has been validated by the Association for the Advancement of Medical Instrumentation (US) and the British Hypertension Society (UK).

The device is very simple to use – a blood pressure cuff is wrapped around the arm of your child and he/she wears it for 24 hours. This cuff is connected to a small computer about the size of a small book which your child will carry. This device automatically measures blood pressure every half an hour for 24 hours. Your

child can carry on with normal activities and he/she will be asked to fill in a diary of the activities for that day. We will teach your child and you or your caregiver how to take off the cuff so that he/she can shower and how to put it on again. The device is taken off after 24 hours. We will collect the device from your child the following day at school/home. That will be the end of the participation in the study. We will try to use all the measurements taken during the 24 hour period. We will need to have at least 14 blood pressure readings in the daytime and 7 readings at night. Blood pressure readings that are physiologically impossible, that is, either much too high or too low for it to be physically possible, will be excluded from the study.

Ways to carry the ABP machines



4. WHO CAN PARTICIPATE?

All students can participate so long as they are not on medication that can affect blood pressure e.g. steroids, or have an illness that can affect blood pressure e.g. kidney problems.

5. YOUR RESPONSIBILITIES IN THIS STUDY

The ABP machine is a very expensive machine. Please handle it with care. If you want to take off the machine for any reason, please simply remove the cuff from your arm. This device is not waterproof. Please take it off before bathing and avoid swimming. Please do not DROP the machine or try to DISMANTLE any portion of the machine. Please return the machine to us the next day.

6 POSSIBLE RISKS AND DISCOMFORTS

There is no foreseeable risk to your child. There should be minimal discomfort. It should feel the same as a normal blood pressure check.

If the cuff becomes uncomfortable, we will teach your child and caregiver how to stop the monitor.

If the cuff slips out of place, we will teach your child and caregiver how to reposition the cuff correctly.

7. POSSIBLE BENEFITS

The study will enable the doctors to establish normal blood pressure ranges in our local children both by office blood pressure measurements as well as by ABP standards. This will enable doctors to more accurately diagnose and treat children with high blood pressure.

Although this is a research project, children who participate in it will essentially be undergoing a blood pressure screen. It is currently recommended by the American Academy of Paediatrics that all children

have their blood pressure checked each time they visit a doctor. Blood pressure screening is currently not yet part of the medical check carried out by the School Health Service when children are in Primary One and Primary Six. Parents of children who are found to have a high blood pressure during this study will be informed of the results and advised on necessary tests.

8. CONFIDENTIALITY

All the results of this study will be kept confidential and records will be kept in a password-protected database. Records will be assessed only by the investigators. However, records might be inspected by the hospital regulatory boards and the hospital internal review board.

9. TREATMENT AND COMPENSATION FOR INJURY

If you follow the directions of the doctors in charge of this study, and you are physically injured due to the procedure, NUH will pay the medical expenses for the treatment of that injury.

10. CONTACTS FOR QUESTIONS OR PROBLEMS

Should you have further questions about the study or need to contact someone in the event of a research-related adverse event, please contact

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For an independent opinion, you may contact Sujatha Sridhar from the National Healthcare Group Domain-Specific Review Boards at telephone 6471 3266.

11. WITHDRAWAL FROM STUDY

Participation is voluntary and your child can discontinue from the study without being penalized.

12. REIMBURSEMENTS / COSTS INVOLVED IN STUDY

Your child will retain his/her legal rights. This will not release the parties involved in this study from negligence, even if the consent form is signed.

There is no extra cost incurred and no reimbursement will be made for transport, time and payment that may result from participation in this study.

To participate in this study, we will require you to sign the consent forms. By signing, you are confirming the following:

1. You have read and understood the purpose of the study.
2. All your questions have been answered to your satisfaction. If you do not understand any of the words, you may ask the doctor or nurses to explain them to you in your own language.
3. You voluntarily agree for your child to participate in this study.
4. You understand that you may freely choose to stop your child from being a part of this study at any time.
5. You have received a copy of this Parent and Child Information and Consent Form to keep for yourself.

**Department of Paediatrics
National University Hospital
5 Lower Kent Ridge Road
Singapore 119074**

CONSENT FORM for Office Blood Pressure Measurements (for students between 12 and 16 years old)

For parent and child:

I, _____ with IC/passport number _____
(name)

agree/do not agree to participate in this study by the Department of Paediatrics, National University Hospital. I understand that my **height, weight and office blood pressure** will be recorded.

Parent's or Guardian's Name: _____ NRIC : _____

Relationship : _____

Signature : _____ Date : _____

Student's Name : _____ NRIC/: _____

Signature : _____

Date : _____

Principal Investigator / Investigator: _____

Signature : _____

Date : _____

Witness's Name : _____

Signature : _____

Date : _____

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CONSENT FORM for Ambulatory Blood Pressure Measurements (for students between 12 and 16 years old)

For parent and child:

I, _____ with IC/passport number _____
(name)
agree/do not agree to participate in the **ambulatory blood pressure** (ABP) monitoring part of this study
by the Department of Paediatrics, National University Hospital. I understand that my blood pressure will be
monitored using the Spacelabs 90217 ABP monitor for 24 hours.

Parent's or Guardian's Name: _____ NRIC : _____

Relationship : _____

Signature : _____ Date : _____

Student's Name : _____ NRIC/: _____

Signature : _____

Date : _____

Principal Investigator / Investigator: _____

Signature : _____

Date : _____

Witness's Name : _____

Signature : _____

Date : _____