Wake Forest®
School of Medicine

Department/Section of Pediatrics/Nephrology

The Role of the Renin-Angiotensin System in Pediatric Essential Hypertension

Informed Consent Form to Participate in Research
Andrew South, MD MS, Principal Investigator

INTRODUCTION

Your child is being asked to participate in a research study. Research studies are done to get information that may help other people in the future. Your child is being asked to take part in this study because they have high blood pressure, and he or she is getting care in the clinic. Their participation in this study is voluntary. You can decide not to allow your child to be in the study, even after your child is enrolled, at any time during the study. There will be no penalty to you or your child, and your child will not lose any benefits. Your child's regular medical care at the clinic will not be affected in any way if you decide not to allow your child to be in the study. Ask the study doctor or the study staff to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand what causes high blood pressure in kids and how high blood pressure can cause damage to the heart and kidneys. We also hope to see how obesity affects high blood pressure.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We will study 50 children with obesity in addition to 100 children that have high blood pressure and 10 children that do not have high blood pressure. We will study children 5 – 17 years of age over a one year period.

WHAT IS INVOLVED IN THE STUDY?

We will collect data from your child's electronic medical record. This will include his/her height, weight, age, sex, race and medical and family histories. Your child will be seen in clinic every three to six months to monitor their blood pressure, as they would if they were not in the study. We will also note the kind of medicine your child takes plus the amount. In addition to the regular tests that are run at each clinical visit, we will run some additional tests to check on kidney function and obesity-related diseases. All samples will be collected at the same time as routine labs, so there will be no blood draws just because of the research study. We will collect less than a teaspoon (5 mL) of blood for the study sample.

If you agree to allow your child to participate in this study, your child's blood/urine sample will be kept and may be used in future research. Your sample will be collected in clinic at Wake Forest University Baptist Medical Center. The sample will be stored in the Department of Pediatrics with a study number and date collected. No genetic testing will be done on these samples. The samples will only be given to researchers approved by Dr. Andrew South. An Institutional Review Board (IRB) must also approve any future research study using your child's sample. We do not plan on contacting your child after the end of this study.

Your child's blood/urine sample will be de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, etc., of the person who donated the sample.

The research that may be performed with your child's blood/urine sample is not designed to help them directly. There is no personal benefit to your child from taking part in this research study. It might help children who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your child's blood/urine will not be given to you or your doctor. The results will not be put in your medical record. The research using your child's blood/urine sample will not affect their care.

Your child's blood/urine sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you or your child which may occur as a result of the research.

_____ Yes, you may store my child's samples for future studies.

_____ No, you may not store my child's samples for future studies.

If you change your mind, we ask that you contact Dr. South in writing at:
Andrew South, MD MS
Wake Forest University Health Sciences, Department of Pediatrics
Medical Center Blvd.
Winston-Salem, NC 27157

How Long Will I Be in the Study?

Your child will be in the study for one year.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than your child's regular care. Samples for this study are only collected when your child is getting labs drawn anyway.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure

and allowing only authorized people to have access to research records, will be made to keep our child's information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your child is not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other children in the future.

WHAT ALTERNATIVES TO PARTICIPATION ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study tests and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL INFORMATION ABOUT MY CHILD BE KEPT PRIVATE?

In this research study, any information we collect or get from your child's medical record about your child's health is considered Protected Health Information. The information we collect for this research study includes: past medical and family histories, blood pressure measurements medications and dosage and laboratory values.

If this research study involves the diagnosis and treatment of a medical condition, the Protected Health Information collected about your child during this study will be placed in his/her medical record, and may be used to help treat him/her, arrange payment for his/her care, or assist with Medical Center operations.

We will make every effort to keep your child's Protected Health Information private. We will store records of your child's Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your child's personal health information and information that identifies your child ("your child's health information" may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your child's health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers, the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your child's health information. If disclosed by them, your child's health information may no longer be covered by federal or state privacy regulations. Your child's health information may be disclosed if required by law. Your child's health information may be used to create information that does not directly identify your child. This information may be used by other researchers. Your child will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your child's Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your child's Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from your child in this study will be kept in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your child's Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Andrew South that you want to take away your permission to use and share your child's Protected Health Information at any time by sending a letter to this address:

Andrew South, MD MS
Wake Forest University Health Sciences
Department of Pediatrics
One Medical Center Blvd.
Winston-Salem, NC 27157

However, if you take away permission to use your child's Protected Health Information he/she will not be able to be in the study any longer. We will stop collecting any more information about your child, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your child's Protected Health Information for this study.

Laboratory test results and other medical reports created as a result of your child's participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

This authorization is valid for six years or five years after the completion of the study, whichever is longer.

The results of this study may be published or presented at professional meetings, but your child's name will not be used or associated with the findings. The data for this study will be kept for a minimum of 3 years after the completion of the study.

WILL YOUR CHILD'S REARCH RECORDS BE CONFIDENTAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your child's identity and/or your child's personal information will not be disclosed except as authorized by you, required by law, or to protect the safety of your child or others. However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your child's identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

Your child will not receive payment for being in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. Your child may choose not to take part or leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which your child is entitled.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Andrew South, MD MS at (336) 716- 9640.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to allow my child to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about my child being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm