Wake Forest®
School of Medicine

Department/Section of Pediatrics / Nephrology

Research Study Parent Permission Form

Pediatric Hypertension Registry (PHREG)

Andrew South, MD MS, Principal Investigator

Introduction

You are being asked to allow your child to take part in a research study carried out by Dr. Andrew South. Please read this form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. This study has been approved for human subjects to take part by the Wake Forest University Health Sciences Institutional Review Board.

You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason. Your child will also be asked if he or she would like to take part in this study. Even if you give your permission, your child can decide not to be in the study or to leave the study at any time.

What is this research study about?

This research study is being done to create a database of patients with pediatric hypertension ("high blood pressure") to improve our understanding and treatment of this important disease.

We are asking your permission for your child to be in the study because your child has been diagnosed with hypertension. There are no study-specific assessments, visits or samples to be collected. All database information will be obtained from the electronic medical record and will not involve any additional time outside of your routine care.

How Many People Will Take Part in the Study?

2000 people from Brenner Children's Hospital Pediatric Nephrology clinic will take part in this study.

What will my child be asked to do if he or she is in this research study?

If your child takes part in the study, all information for the database will be collected from their electronic medical record. They will be assigned a study ID. All data will be de-identified and stored securely.

How long will my child be in this study?

Your child will be in the study for about 10 years or until they no longer associated with the Pediatric Nephrology clinic.

Your child can stop participating at any time.

Are there any benefits to my child if he or she is in this research study?

There is no direct benefit to your child from being in this study. We hope that information learned from this study will benefit other people with your condition in the future.

Are there any risks to my child if he or she is in this research study?

Your child's medical care will not change because you are taking part in the registry. You and your child's doctor will keep making all the decisions about their treatment and care.

The potential risks to your child from taking part in this study are a slight risk of breach of confidentiality. We will do our best to protect your child's confidential information. Your child may stop participating in this registry at any time.

What alternatives to participation are there?

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

Will information about my child be kept private?

In this research study, any information we get from your child's medical records or other facilities about your child's health or behaviors is considered Protected Health Information. The information we will collect for this research study will come from your child's electronic medical record. That includes**:** gender, parent-reported race, height, weight, body mass index, age at diagnosis, age at each visit and past medical and family histories. We will record all blood pressure monitoring as well as all medication types and dosages. We will record standard clinical laboratory values. We will also record results from echocardiograms and ultrasounds.

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.

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 or will be kept for an indeterminate period of time. This authorization does not Expire. 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
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.

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

The data for this study will be kept private and confidential to the extent allowed by federal and state law. All study data will be de-identified and stored securely in an encrypted system.

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.

Are there any costs or payments for your child being in this research study?

Your child will receive no payment or other compensation for taking part 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

Will your child's research records be confidential?

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 health 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.

What are my child's rights as a research study volunteer?

Your child's participation in this study is completely voluntary. Your child may choose not to take part in this study, choose not to answer specific questions, or leave the study at any time.

There will be no penalty or loss of benefits to which you or your child are entitled if you choose not to give your permission for your child to take part or your child withdraws from the study.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Who can I talk to if I have questions?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Andrew South 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 signed copy of this consent form.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved for your child.
- You understand that even if you give your permission, you child may choose not to take part in the study.

Wake Forest®
School of Medicine

Statement of Consent

I give my voluntary permission for my child to take part in this study. I will be given a copy of this consent document for my records.

Signature of Parent/Guardian_____ Date: _____Time:_____ am pm

Printed Name of Parent/Guardian:_____

Printed Name of Minor:_____

Statement of Person Obtaining Informed Consent

I have carefully explained to the parent of the child being asked to take part in the study what will happen to their child.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of his or her child's participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means for his or her child to take part in this research.

Signature of Person Obtaining Consent:_____Date:_____ Time:_____am pm

Printed Name of Person Obtaining Consent:_____