Official Title: Improving Screening and Therapy Provision Among Hispanics/Latinx at Risk for Chronic Kidney Disease

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Improving Screening and Therapy Provision among Hispanics/Latinx at Risk for Chronic Kidney Disease

CONCISE SUMMARY

The purpose of this study is to identify Hispanic/Latino individuals in North Carolina who might have kidney disease or are at risk for kidney disease. Participants will be screened for high blood pressure, overweight or obesity, family history of elevated blood sugar (diabetes) or signs of kidney disease (protein in their urine). The goal of this study is to increase awareness of kidney disease for Hispanics/Latinos in Durham and provide education to those people. If we can identify people who have kidney disease or those at risk early on, we can offer resources to help slow the progression of kidney disease.

During the screening event, your participation will last approximately 20-30 minutes. If you agree to a follow-up contact, this will occur after about 1-3 months from the screening event. The follow-up contact will last no more than 30 minutes.

If you are interested in participating in this study, more details about participation are provided below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Matt Sinclair will be your doctor for the study. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Sinclair's and his research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify Hispanic/Latino individuals in North Carolina who might have kidney disease or are at risk for kidney disease. Many people who have sick kidneys, known as chronic kidney disease (CKD) don't know it. Hispanics/Latinos tend to have more rapid decline of their kidney function

compared to non-Hispanics. The goal of this study is to increase awareness of kidney disease for Hispanics/Latinos in Durham and provide education to those people. If we can identify people who have kidney disease or those at risk early on, we can offer resources to help slow the progression of kidney disease. Specifically, we are looking to identify Hispanics/Latinos with high blood pressure, those who are overweight or obese, those with a family history of diabetes or kidney disease, and those with protein in their urine, as these are groups that are more likely to have kidney problems. You are being asked to be in the study because you have identified yourself as Hispanic/Latinx and you are participating in an activity in your community that is focusing on health and wellness. There is a chance that you may benefit from learning more about kidney disease and if you are at risk for kidney disease, so something can be done to help.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 200 people will take part in this study at Duke. We expect to enroll about 50-75 people at each screening event.

WHAT IS INVOLVED IN THE STUDY?

If you choose to join the study, you will be asked to sign and date this consent form. We will conduct a short survey asking about you and some of your medical history. You have already had your blood pressure, height, and weight as part of the routine screening with the community workers today. We will record this data and you will also provide a urine sample in a cup (any amount of urine, even a few teaspoons) and we will test it to see your risk of having kidney disease. We test it for certain things such as protein and sugars, and then destroy any leftover samples. When we collect your urine sample, we will assign it with a unique ID number to protect your identity. Only the researchers in this study would be able to identify you with your unique number. Urine samples will not be stored for future use.

A research team member will discuss your results with you and provide you with recommendations for further action. This may include recommendations for changes in your diet or other behavior changes, and may include giving you a list of doctor's offices to visit to discuss your results more with a nurse or doctor.

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If you provide us with your contact information, a study team member will contact you in about 1-3 months to ask you some questions. This information helps the study team know if this study has been helpful. You may choose not to answer any question.

WHAT ARE THE RISKS OF THE STUDY?

There are very minor risks in this study. These include the following:

1). There is a rare chance that you will have an emotional or distressing feeling from your screening results. You may encounter this if you have family members who died from CKD or are on dialysis. All screenings are conducted in private and time is allowed to talk about the results.

2). If for some reason you are unable to generate a urine sample, you may feel frustrated about this. Reassurance is provided as is water, and you are encouraged to return when the sample is available. You will also be reassured that a primary care provider can order this same test for you if you cannot make a urine sample today.

3). Loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Research is designed to benefit society by learning new things. The benefits to you from being in this study include learning more about kidney disease through conversations with the study team and educational materials. You may also benefit by learning whether you are at risk for kidney disease, and if so, how to get an appointment with a primary care provider in the community.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Instead of being in this study, you can choose to schedule your own CKD screening with your doctor. Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those

collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with NIH and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of NIH,
- Duke Center for REACH Equity,
- the Duke University Health System Institutional Review Board,

If any of these groups review your research record, they may also need to review your entire medical record.

The family history survey and urine test are being done only because you are in this study. The study results will be provided to you.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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The NIH has issued a Certificate of Confidentiality (CoC) to further protect your privacy. This means that Dr. Sinclair cannot release or use information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, like a court order. There are some important things that you need to know about CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

WHAT ARE THE COSTS TO YOU?

There are no costs to you for participating in this study. You and your insurance company will not be billed for your participation.

WILL I BE PAID TO BE IN THE STUDY?

For your participation you will be compensated with a gift valued at no more than $10.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

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For questions about the study or research-related injury, contact Matt Sinclair at 919-668-0113 during regular business hours and at 919-668-0113 after hours and on weekends and holidays.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY?

If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Matt Sinclair in writing and let them know that you are withdrawing from the study. His mailing address is 300 W. Morgan Street, Durham, NC 27701.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns, contact Dr. Matt Sinclair at 919-668-0113 during regular business hours or by email at matthew.sinclair@duke.edu

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Are you interested in being contacted in ~1-3 months to answer a few questions about this screening and what you have done in the meantime?
__ Yes
__ No

What is the best phone number to contact you, or your caregiver, for follow-up questions?
Telephone Number 1_____
Telephone Number 2_____

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Is it okay to contact you in the future if we have another research study we think you may be interested in?
__ Yes __ No

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Research Participant

_____ _____ _____
Signature of Person Obtaining Consent Date Time