Screening and Access to Health Care for Vascular Disease in Urban and Suburban Patient Populations

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CONSENT FORM

Screening and Access to Health Care for Vascular Disease in Urban and Suburban Patient Populations

Primary Investigator: Dr. Navyash Gupta

Primary Investigator telephone number: (847) 663-8050

Sponsor: NorthShore University HealthSystem

Financial Supporter: MEDTRONIC

EXPLANATION OF STUDY:

Introduction: You are being asked to volunteer for this clinical research study because you are at least 55 years of age and have responded to our advertisement about the study.

This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help your decision. If you have any questions, you can ask the research study doctor and/or staff.

Why is this Study Being Done?

The main purpose for this study is to determine if there are differences in access to health care, in particular, care for diseases of the blood vessels, in three different Chicagoland areas. This study will also allow us to determine how common and widespread vascular disease (blockage of the blood vessels) is in three different Chicagoland neighborhoods.

This study will include a total of 255 subjects with around 85 from the north suburbs and 85 each from the south and west sides of Chicago

What Will Happen During the Study?

You will be here about 2 hours today to complete an interview about your health and to have 3 scanning tests. We will then call you by phone six (6) times: six (6) months later and then every year at year 1, 2, 3, 4, and 5.

After you have signed this consent form, the screening today will include the following:

1) You will be asked to provide your:
   - age
   - date of birth
   - race
   - ethnicity
   - contact information
   - your physician's name

- your personal and family health history
- your social habits
- your education
- what type of health insurance you may have (private, government).

This will take about 15 minutes.

2) You will be asked to complete a Questionnaire provided by the Life Line Screening Company and sign their required HIPAA release forms. (5 minutes) The questionnaire will ask questions regarding your current health and your health history. The HIPAA release acknowledges that you are aware that we are collecting your personal information it will be shared with screening company, our research team and the company supporting this research.

3) Your blood pressure, pulse and breathing rate will be taken. (5 minutes)

4) Your height and weight measured.

5) You will be asked to have some tests that will look for common problems people have with their blood vessels. To screen for these problems, we will take pictures of your blood vessels with an ultrasound and measure your blood pressure. An ultrasound is a machine that takes pictures of your arteries by bouncing sound waves and recording the echoes. Three ultrasound tests will be done: one on your belly, one on your neck and one on your legs.

You will be asked to lift your blouse or shirt so the ultrasound probe can be rubbed on your belly. The ultrasound probe will be used on both sides of your neck. You will feel some mild pressure from the probe. During the third test, we will ask you to lie down and let us apply and squeeze blood pressure cuffs around your arms and legs. We will use ultrasound to help us hear the blood flowing in your arms and legs, so we can get accurate readings of the difference in blood pressure between your arms and legs.

If the test results show that you have serious problems with your blood vessels, a copy of the ultrasound will be given to you on the day of the test. You will be advised to see your doctor as soon as possible. Otherwise, you will receive the results of the test in about 3 weeks. You are asked to share the test results with your doctor.

We will call you a total of 6 times:

- in six (6) months
- and once each year for five years

During these calls, a research team member will ask you questions about:

- your health,
- any medications you are taking,

- or if you have received medical treatment for problems with your blood vessels (vascular disease).

Each phone call will last about 20 minutes.

We will call you at a time that is good for you. It is very important that we have your correct phone number and a back up emergency number so we are able to reach you.

If you receive any treatment for vascular disease during the study, Dr. Gupta may ask if he can talk to your physician(s) about your treatment. If this happens, you will be asked to sign a separate permission form.

What Other Choices Do I Have?

This is a research study and does not involve treatment. The alternative is not to participate.

Are There Benefits to Taking Part in the Study?

This study will allow doctors to learn more about how much vascular disease there is, and how it is being managed and treated in each of the neighborhoods. Knowledge gained in this study may help people in the future. You will receive a final report with your test results in the mail in about 3 weeks.

What Side Effects or Risks Can I Expect?

Ultrasound is a noninvasive test that, when used properly, has not demonstrated harm. The long term effects of repeated ultrasound tests are not fully known, but we believe this is a harmless test with no long term side effects.

There is a 5-year commitment to follow-up phone calls for this study. This may be inconvenient but our team will do everything possible to make sure that we call you at times that are convenient for you.

There is a possibility that, as a result of this screening, you may discover that you have a medical condition that should be treated by a doctor. This may cause some feelings of stress and anxiety.

Reproductive Risks:

There are no known reproductive risks with ultrasound.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study and by the company paying for the research. Your research file can also be looked at by the NorthShore Institutional Review Board, other medical personnel at NorthShore who are involved in your care, or by the Food and Drug Administration (FDA).

You will be asked to sign a release allowing Life Line Screening to provide a copy of your test results and questionnaire to the study doctors. If you do not sign this release, you will not be able to participate in the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will I Be Paid for Participating?

You will not be paid for being in this study.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study during the screening visit. You will still be responsible for all costs that would happen as part of routine care should you need to seek medical care after the screening.

Can I Withdraw From the Study?

Your participation in this research study is voluntary. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

Your doctor or the sponsor may stop this study or take you out of the study without your permission.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call With Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Project Director, Dr Navyash Gupta, at telephone: (847) 663-8050.

INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that Dr. Navyash Gupta and his assistants will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study director and/or staff. I have had enough time with the study director and/or staff to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	

Authorization for the Release of Protected Health Information

The Federal Government created a rule called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the privacy of your protected health information (PHI). Your protected health information is information about you that could be used to find out who you are. For this research study, this includes information in your medical records needed for this study. It also includes new information created or collected during the study.

This Data Privacy Statement explains how your PHI will be used and who it will be given to for this research study. It also describes your privacy rights, including your right to see your protected health information.

By signing this form, you will give permission ("authorization") for the use and disclosure of your PHI that is described in this document. If you do not want to allow these uses, you should not participate in this study. You will not be allowed to participate if you do not sign this form.

If you agree to be part of the research study, your protected health information (PHI) will be used and disclosed in the following ways:

<u>What Protected Health Information Will Be Used?</u>

- The study Investigator and staff will use your medical records for the study. They will also use information collected during the study. This will include the results of any medical tests, procedures, or questionnaires completed during the study. Your information will only be used for the purposes described in the Consent Form.

<u>To Whom Will This Information Be Disclosed?</u>

- The study Investigator and staff may give your study-related PHI to the following
    - The study financial supporter
    - Other investigators in the study
    - Regulatory authorities in the United States and other countries
    - The Institutional Review Board overseeing this study

- The study-related PHI disclosed will not include your name, address, social security number, or other information that *directly* identifies you. Instead, a code number will be attached to your PHI. In some cases your initials may be used.

- Study data that does not directly identify you may be published in medical journals. It may also be shared with others as part of scientific discussions.

- The financial supporter, MEDTRONIC, and the Review Board in charge of this study may look at your medical records. Government employees of the United States and

other countries could also look at your records. These records might contain information that identifies you. The purpose of this is to assure the quality of the study, or for other uses allowed by law.

- The financial supporter, MEDTRONIC and the Investigator will not disclose PHI to insurance companies unless required to do so by law. You could be asked to give separate written authorization to do so.

Your PHI may no longer be protected under the HIPAA privacy rule once it is given to these other parties.

Do I Have Access To My Protected Health Information?

You have the right to see and copy your personal health information related to the research study. You have this right for as long as this information is held by the study Investigator. However, to protect the study, you will not be able to see some of the study information until after the study is completed.

Cancelling Permission

You may cancel permission for use of your health information at any time. You can do this by giving written notice to the study Investigator. If you cancel your permission, the Investigator and staff will no longer use your information for this study. The sponsor, NorthShore University HealthSystem, and/or Investigator will still use data that was collected before you canceled your permission. If you cancel, you will no longer be able to be in the study. However, you will not be penalized or lose any benefits to which you are entitled.

Your authorization for activities described in this form does not have an expiration date.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	