The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Evaluation of a Novel Technique to Diagnose Carotid Artery Stenosis (CAS)
Funding Support Provided by CVR Global
Principal Investigator: Dr. Heather Gornik, Phone number: (216) 445-3689
Co-Investigator: Dr. Imad Bagh, Phone number: (216) 636-6918
After hours phone contact #: (216) 444-2200, ask for the Vascular Medicine fellow on call

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

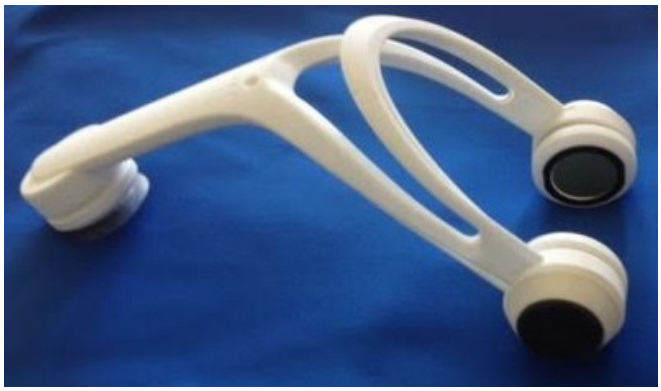
Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

- The purpose of this study is to determine the accuracy of a new non-invasive device, the Carotid Stenotic Scan (CSS), to check for blockage of the internal carotid artery (ICA) as compared to a carotid ultrasound study. The CSS is a non-invasive device that detects movement or vibration of blood flow in the arteries and estimates the degree of blockage (if any) that is present. The CSS is shaped like a stethoscope with 3 small pads (see picture). It is positioned with a gel pad on either side of your neck and one



on the front of your chest. The scan takes about 1-2 minutes. The scan device pads lay on your skin and do not use any invasive techniques or radiation to provide the image.

Why are you being asked to take part in this research?

You are being asked to take part in this study because you are undergoing a carotid ultrasound in the vascular laboratory. Your health provider has ordered a carotid ultrasound test. The carotid arteries are located on each side of the neck and circulate blood flow to the head and brain. These arteries can become narrowed or blocked for a variety of reasons, including atherosclerosis (plaque) or another artery condition called fibromuscular dysplasia (FMD). Carotid ultrasound scans are good tools to measure the degree of narrowing of the carotid arteries and for this study will be used to help judge the accuracy of the CSS.

How many people will take part in the study?

This study will enroll 300 people seen in the outpatient Cleveland Clinic Non-Invasive Vascular Laboratory.

What is involved if you decide to take part in this research study?

- After informed consent is obtained, a medical history will be obtained by a member of the study team. You will be asked some questions about your health and medications and your medical record will be reviewed. We will ask you your height and weight.
- After the questions, you will undergo a scan utilizing the CSS device. The CSS scan can be performed either before or after your scheduled carotid ultrasound that your provider had ordered.
- Aside from the normal amount of time required for your carotid ultrasound, it is expected that the entire CSS portion of the research will take approximately 15 minutes.
- Within 3 months following your ultrasound and CSS scan, a member of the research team will review your medical record to note any other imaging studies that have been done to check your carotid arteries, and the these findings will be recorded. This does not require another visit or contact with the study team. After this time, your participation in the study will be concluded.
- The study described is for research purposes only. It is not the purpose of the CSS device to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness that is not already determined by carotid ultrasound testing. Therefore, you will not receive results from the CSS device readings.
- Data will be shared with the sponsor, CVR Global. The only personal identifying information that will be provided to CVR Global will be your age, initials, date enrolled, and date of any follow-up studies. If there is a discrepancy between what the CSS reads and what your standard carotid ultrasound or other imaging studies report, the images may be sent to the sponsor for review.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative is not to participate in this study.

3. RISKS

What are the risks of participating in the research study?

This is a low risk research study. The CSS device is non-invasive and passive. You may experience mild discomfort resulting from device placement on your skin. While there are no physical risks associated with this study, there is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential through the use of storing data in a password protected computer accessible only by the research team, however, this cannot be guaranteed. In the unlikely event of a study-related adverse event, the Principal Investigator, IRB and sponsor (CVR Global) will be notified.

4. BENEFITS

What are possible benefits of participating in the research?

There will be no direct benefit to you for your participation. There may be a benefit to society as a whole in helping to develop new tools for noninvasive means to diagnose carotid artery disease. The knowledge to be gained from this research may be beneficial for other patients, society, or science.

5. COSTS

Are there any costs to you if you participate in this study?

There are no additional costs to you for your participation in this research study. The CSS scan and other study related procedures will be provided at no cost to you. The cost for the carotid ultrasound test and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

There are no plans to provide financial compensation to you in the event the results from this research lead to the development of new products.

6. COMPENSATION

Are there any payments to you if you participate in this study?

Study participants will receive a parking pass.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or

give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**, Heather Gornik, MD at the Cleveland Clinic, 9500 Euclid Avenue Desk J3-5, Cleveland, OH 44195.** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

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

8. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

- This study is funded by CVR Global and Drs. Bagh and Gornik have received funding to conduct the study at Cleveland Clinic.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Heather Gornik, the Principal Investigator, at (216) 445-3689. For any problems that develop after hours, Dr. Gornik or the vascular medicine fellow is on call 24 hr/day and can be reached at (216) 444-2200. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

We may stop the study at any time. If this happens, it is because we are unable to record measurable data with the CSS device due to unforeseen events (i.e. excess patient movement or device malfunction).

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____

Printed name of Participant

_____ _____

Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____

Printed name of person obtaining consent

_____ _____

Signature of person obtaining consent Date