

# UNIVERSITY OF WASHINGTON CONSENT FORM

## Atherosclerotic Plaque Neovascular Inflation

ULTRASOUND STUDY OF ARTERIAL PLAQUE

### RESEARCHERS:

Name	Title	Division/Department	Telephone
Kirk W. Beach, PhD, MD	Research Professor	Vascular Surgery	206 598-9766
Yongmin Kim, PhD	Professor	Bioengineering	206 685-2271
R. Eugene Zierler, MD	Professor	Vascular Surgery	206 598 9851
Dan Leotta, PhD	Res Asst Professor	Vascular Surgery	206 598 9761
John Kucewicz, PhD	Research Engineer	APL/CIMU	206 221 3283
Barbrina Dunmire, MS	Research Engineer	APL/CIMU	206 685 6953
Marla Paun	Vascular Technologist	APL/CIMU	206 221-4731
Jean Primozich	Vascular Technologist	Vascular Surgery	206 598 9766
Edward Stutzman, RVT	Vascular Technologist	Vascular Surgery	206 598-9759
Wendy Hamar	Research Scientist	Vascular Surgery	206 616 8369
Ruthanne Naranjo, BS	Program Operations Mgr	Vascular Surgery	206 598-9766
Siddhartha Sikdar, PhD	Senior Fellow	Bioengineering	206 221 5168
Vijay Shamdasani, MS	Graduate Student	Bioengineering	206 221 5225
“Charles” Canxing Xu	Graduate Student	Bioengineering	206 221 5225

APL/CIMU = Applied Physics Laboratory, Center for Industrial and Medical Ultrasound

### **Researchers’ statement**

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

### **PURPOSE OF THE STUDY**

Arteries can be obstructed by atherosclerotic plaques. Some plaques cause problems such as stroke, pain with exercise or skin breakdown. The purpose of this research is to find the differences between those plaques that cause problems and those that do not. In this study we will look at the blood supply to the tissues inside the plaque. We think that blood supply may relate to problem plaque.

### **STUDY PROCEDURES**

You are having an ultrasound procedure for your clinical care. If you chose to take part in this research study, we will perform an ultrasound procedure that is similar to the clinical ultrasound. The ultrasound procedure for this study will examine your arteries with plaques. The study procedures will take about one additional hour.

We will first ask you several questions about your medical history that may relate to the development of plaques in your arteries. We will not look at your medical records. We may ask you questions about your history of tobacco use, if you have diabetes, high blood pressure, high cholesterol and whether you have had any strokes or heart attacks. We may ask you if you take aspirin, anti-inflammatory drugs such as ibuprofen, or anti-coagulants such as Coumadin. We may also ask you about any surgeries you have had such as bypass surgery or angioplasty to treat plaques in your arteries.

**UNIVERSITY OF WASHINGTON CONSENT FORM**

**Atherosclerotic Plaque Neovascular Inflation**

ULTRASOUND STUDY OF ARTERIAL PLAQUE

We may attach ECG patches to your arms and a band around your chest to detect the timing of your heartbeat and respiration. We may measure the blood pressure in your arms or legs using a blood pressure cuff and pressure meter. We will apply ultrasound gel to the skin over your arteries in your neck, arms or legs. We will ask you to lie still while we hold the ultrasound probe for each measurement. Each measurement will take about 30 seconds. Between measurements, we want you to keep the same position.

You may rest at any time. If you need to change positions, please let us know, and we will accommodate you. You can stop the study procedures at any time.

**RISKS, STRESS, OR DISCOMFORT**

There are no known physical risks for ultrasound procedures. However, you may become tired or uncomfortable. In that event, please let us know. You can stop the study procedures at any time.

**ALTERNATIVES TO TAKING PART IN THIS STUDY**

If you choose to not take part in this research study, you will not have an ultrasound procedure for the purpose of this research study. In that case, we will not ask you questions about your health history. Your clinical care will not change whether or not you choose to participate in this research study.

**BENEFITS OF THE STUDY**

You will not directly benefit from taking part in this study. We hope the results of this study will help us tell the difference between plaques that will cause problems from those that will not cause problems.

**OTHER INFORMATION**

Taking part in this study is voluntary. You can stop at any time. Your clinical care will not change whether or not you choose to participate in this research study. Information about you is confidential. There will be no link between your identity and the ultrasound measurements and personal information we collect. We will not maintain a link between your name and the study information. If we publish the results of this study, we will not use your name. The results of this study may also be used for future, related studies.

If you suffer a physical injury as a direct result of being in this study, we will treat you. We will provide this treatment at no cost to you, within the limits of the University's compensation plan.

---

Printed name of study staff obtaining consent                      Signature                      Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

---

Printed name of subject                      Signature of subject                      Date  
Copies to:      Researcher, Subject