GCO # 06-1269

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT:

Accuracy of Bedside Ultrasonography in Diagnosing Upper Extremity Venous Thromboses

A. PURPOSE OF THE STUDY:

You are being asked to participate in a research study. The purpose of this study is to determine if bedside ultrasound can be used to accurately diagnose upper extremity blood clots. You qualify for participation in this study because your doctor has scheduled you for a test to check for a blood clot in your arm.

B. DESCRIPTION OF THE RESEARCH:

200 people are expected to participate in this study. If you agree to enroll in the study, you will be asked a few background questions (name, age, race, etc.) and a bedside ultrasound test will be performed during your regularly scheduled visit to test for blood clot. The bedside ultrasound test is being performed for research purposes, and your regularly scheduled vein mapping procedure is being performed as part of your standard clinical care.

The ultrasound test will be performed by a study doctor and should last about ten minutes. The test involves placing a probe with gel on it next to your skin to get a picture of the veins. At the end of the test, your participation in the study will be complete. The results of the bedside test will be compared to the results of the radiology department test to determine how accurate the bedside test is. You will not be informed of the results of the bedside ultrasound test; you will be informed of the results of today's vein mapping study by your doctor.

C. COSTS/REIMBURSEMENTS:

There will be no additional costs incurred in this study. No reimbursements will be applied for participation in this study.

Subject/Surrogate Initials _____

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D. POTENTIAL RISKS AND DISCOMFORTS:

Ultrasound is generally considered a safe test, without risks associated with testing.

E. POTENTIAL BENEFITS:

You may not directly benefit from your participation in this study. In the future, patients being tested for blood clots using ultrasound may benefit from this research.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate. Subjects who choose not to enroll in the study will continue on to formal vein mapping studies as scheduled.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

Subject/Surrogate Initials _____

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If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Bret Nelson at telephone number 212-241-6794.

I. VOLUNTARY PARTICIPATION:

Participation in this study is voluntary. If you decide not to participate, this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, or want to discuss any possible study-related injuries please contact Dr. Bret Nelson, at telephone number 212-241-6794. If you still have questions regarding the study or your rights as a participant in the study you may discuss them with an administrator of the Institutional Review Board at Mount Sinai School of Medicine at telephone number (212) 659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None.

Subject/Surrogate Initials _____

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AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Research Subject's Name (printed):_____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Bret Nelson and his associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Bret Nelson and/or his associates has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

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AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the foregoing drugs, devices or procedures, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such drugs, devices or procedures and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____
Print Name of person who obtained consent Title

Date: _____ Time: _____

Subject/Surrogate Initials _____

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