MOUNT SINAI SCHOOL OF MEDICINE
MOUNT SINAI HOSPITAL
RESEARCH SUBJECT AUTHORIZATION

GCO # 06-1269

Protocol Title: Accuracy of Bedside Ultrasonography in Diagnosing Upper Extremity Venous Thromboses

Principal Investigator: Bret P. Nelson, MD, RDMS
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New York, NY 10029
(212) 241-6794

Co Investigator(s): Jeffrey Olin, DO
Thomas Wu, MD

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. The federal **H**ealth **I**nsurance **P**ortability and **A**ccountability **A**ct (HIPAA) requires us to give you more detailed information about how we intend to use and share your health information in connection with this study. We also need to ask your permission to receive, use and share that information.

You authorize the Mount Sinai Hospital, your doctors and other health care providers to disclose your health information for the purposes described below:

What personal health information is collected and used in this study, and might also be disclosed (shared)?

The following personal health information will be collected, used for research and may be disclosed or released in connection with this research study.

- Name, Medical record number
- Medical History (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Medical Record (including the results of the vein mapping study performed by the Vascular Laboratory today)
- The results of the limited bedside ultrasound study performed by the study doctor

HIPAA Authorization MSH
Reviewed on behalf of Mount Sinai's HIPAA Privacy Officer and approved on 4/9/07.

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Why is your personal health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. This may include monitoring your health status, measuring the effect of drugs/devices/procedures, to determine research results, and possibly to develop new tests, procedures, and commercial products. The research team may use and share your information to ensure that the research meets legal, institutional or accreditation requirements.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other Mount Sinai Hospital and Mount Sinai School of Medicine staff associated with the study).
- The Mount Sinai School of Medicine Institutional Review Board (the committee charged with overseeing research on human subjects) and the Mount Sinai Hospital's and Mount Sinai School of Medicine's Privacy Officers.
- Authorized members of the Mount Sinai Hospital and Mount Sinai School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the Mount Sinai School of Medicine and the Mount Sinai Hospital, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above may disclose your personal health information, including the results of the research study tests and procedures to the following people or organizations. It is possible that there may be changes to the list during this research study. You may request an up-to-date list at any time by contacting the Principal Investigator.

- At this time only investigators from Mount Sinai Hospital are involved in this study; however it is possible that the Department of Health and Human Services or the Office for Human Research Protections (OHRP) may request access to your personal health information

How long will the Mount Sinai School of Medicine and the Mount Sinai Hospital be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you have to sign this Authorization?

NO! If you decide not to sign this authorization you will not be allowed in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your

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permission, the Principal Investigator for the research study may still use your personal information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your personal health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. If you have not already received it, you will also be given the Mount Sinai Hospital - Mount Sinai School of Medicine Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document:

- You are permitting the Mount Sinai Hospital, your doctors and other health care providers to disclose your health information to the researcher for the purposes described above.
- You are permitting the Mount Sinai School of Medicine and the Mount Sinai Hospital to use your personal health information collected about you for research purposes within our institution.
- You are also allowing the investigators, the Mount Sinai School of Medicine and the Mount Sinai Hospital to disclose that personal health information collected about you to outside organizations or people for research purposes as described above.
- You recognize that your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable) and to run the business operations of the hospital.
- You recognize that once information is disclosed to others outside Mount Sinai School of Medicine and the Mount Sinai Hospital the information may be redisclosed and no longer be covered by the federal privacy protection regulations.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2522 or the New York City Commission of Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

_____
Signature of Subject or Personal Representative

_____
Print Name of Subject or Personal Representative

_____
Date

_____
Description of Personal Representative's Authority

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Address:

_____
_____
_____
_____

Telephone:

_____ (daytime)
_____ (evening)

Email Address (optional):

_____

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.

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