GCO # 07-0975

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT:

Ultrasound Lung Comets and BNP in Acute Dyspnea

A. PURPOSE OF THE STUDY:

You are being asked to participate in a research study. The purpose of this study is determine if a sonogram (ultrasound) of the lung can be used to assess heart failure when compared to blood tests and traditional assessment by a doctor. A lung sonogram is a picture of the lungs created with sound waves. You qualify for participation in this study because your symptoms of shortness of breath may be due to congestive heart failure.

B. DESCRIPTION OF THE RESEARCH:

100 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. The bedside ultrasound test is being performed for research purposes and will not interfere in your standard clinical care.

The ultrasound test will be performed by a study doctor and should last about five minutes. The ultrasound test involves placing the ultrasound device with gel on it next to your skin to get a picture of your lungs. This test is not part of standard care, and the results will not be placed in the medical record. At the end of the test, your participation in the study will be complete. The results of the bedside ultrasound test and your standard of care lab tests will be compared to each other and to the clinical assessment of your shortness of breath. This information is being collected from a review of the standard of care tests from your medical record. This is to determine if ultrasound could be useful in making the correct diagnosis of your breathing difficulty.

Subject/Surrogate Initials _____

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C. COSTS/REIMBURSEMENTS:

There will be no cost to you for participating in this research. There is no cost for the ultrasound test. You or your insurance company will be responsible for any tests or treatment done as part of your standard care. You will not receive any reimbursement for participating.

D. POTENTIAL RISKS AND DISCOMFORTS:

Ultrasound is generally considered a safe test, without risks associated with testing. There always exists the potential for loss of privacy. However, we will do everything possible to make sure that the information collected from you remains confidential.

E. POTENTIAL BENEFITS:

You may not directly benefit from your participation in this study. In the future, patients with shortness of breath possibly related to congestive heart failure may benefit from this research.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate. Patients who choose not to enroll in the study will receive standard clinical care.

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.

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H. COMPENSATION/TREATMENT:

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

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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. 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 _____ 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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