IRB APPROVED
CONSENT FORM

SEP 19 2012

St. Luke's-Roosevelt Hospital Center

CONSENT FOR PARTICIPATION IN RESEARCH

_____ Sarah Frasure, MD.
Print name of subject Principal Investigator

Supine versus Upright Patient Position in the Assessment of Pulmonary Ultrasound Findings in Emergency Department Patients with Decompensated Heart Failure
Title of Project

IRB # 12-107

Attached to this form is a full description of the study in which we are asking you to participate. The description tells you about the reason for the study; the procedures, interviews and drugs or devices which may be involved; the duration of the study; and any risks or benefits to you. The description also gives you information about other medical treatments you may receive if you do not want to participate in this study.
If you have questions concerning this research project or your rights as a research subject, or if you have a research-related injury, you may telephone:

Patient Representative at: (212) 523-3700 Principal Investigator at: 212-523-3981

CONSENT TO PARTICIPATE -- ADULT

I have read the attached study description. The purpose of the study, the risks of the study and what it means to participate in the study have all been explained to me, and my questions have been answered. I agree to participate in the study and agree to take all of the tests or procedures mentioned in the study description. If I am injured in the study, I understand only immediate essential medical treatment will be provided free of charge. I understand that participating in the study is voluntary, that I can decline to participate, and that I can stop participating at any time. I also understand that my decision to participate in or to withdraw from the study will not affect the health care I receive, now or in the future. I have been told that records of this investigation will be kept confidential to the extent permitted by law but are subject to inspection by the U.S. Food and Drug Administration and study sponsors.

_____ _____ _____ _____
signature of subject date signature of witness date

_____ _____
signature of authorized representative date relationship to subject

May only be used to enroll subjects until:

SEP 18 2013

I, _____, have clearly and fully explained to the above subject (or person giving consent) the nature, requirements and risks of the study.

_____ _____
Signature of researcher date

DISTRIBUTION:
Original to Research Records, copies for subject (or person giving permission), investigator, and Hospital Chart and Pharmacy where appropriate.

REV 4/19/07

Supine versus Upright Patient Position in the Assessment of Pulmonary Ultrasound Findings in Emergency Department Patients with Decompensated Heart Failure

1. Purpose

You are being asked to participate in this research study because you have a history of chronic heart failure. The purpose of this study is to determine whether physicians can obtain valuable information about the amount of water in your lungs whether you are lying down or sitting upright for an ultrasound study. You are being approached for this study because we would like to see if there is water in your lungs by using an ultrasound machine. Usually we perform the lung ultrasound exam in patients who are lying down, but we realize that sometimes this can make it harder for patients to breathe. We would like to see if it is possible to obtain the same type of information (amount of fluid in the lungs) if we perform the lung ultrasound exam when you are sitting upright.

2. Procedure

First we will place ultrasound gel on your chest over different areas of the lung. We will then place an ultrasound probe on different regions of your chest and look for fluid in the lungs. You will initially have the exam performed while sitting upright. Then you will lie down and we will perform the lung ultrasound exam again. We anticipate that you will be lying flat for about 3-5 minutes. If you become short of breath or develop chest pain while lying down for the second part of the study, we will sit you up immediately and stop the exam. We will take a total of 16 pictures of the lung.

3. Duration

This study takes about 5-7 minutes to perform in the Emergency Department, and you will be able to watch while it is being performed.

4. Risks

There is no radiation associated with ultrasound. The only potential risk associated with ultrasound is an allergic reaction to the gel that we use, which is quite rare. If you develop itching or redness where we place the gel we will treat you for this condition. There is also a risk that you may become short of breath while you are lying flat for the second part of the study, which will take approximately 3-5 minutes. If you become short of breath or develop chest pain while lying down for the second part of the study, we will sit you up immediately and stop the exam.

5. Benefits

No benefits are expected to result for you from involvement in this study. The results of the ultrasound examination will not be used to determine your treatment in the Emergency Department. We do hope that the study will benefit patients who come to the ED with chest pain or difficulty breathing in the future.

6. Alternatives

You may decline participation in the study. You will not receive an ultrasound examination in the Emergency Department without study participation.

7. Confidentiality

If you consent to participate in this research, your personal information will be kept confidential and will not be released without your written permission, except as described in this section or as required by law. Your personal information may be shared, to the extent necessary, among the research staff, with the Institutional Review Board and research oversight staff, and/or with your treating physician or your other health care providers.

Your personal information also may be used and disclosed in the same ways that it may be used and disclosed for regular hospital treatment, payment and health care operations: for example, with your insurance company so that, as appropriate, you may get reimbursed or covered for any medical services you receive.

Your name will not be reported in any publication; only the data obtained as a result of your participation in this study will be made public. If this study involves medications or devices regulated by the Food and Drug Administration (FDA), the FDA and other regulatory agencies, as well as the sponsor of the study, may inspect records identifying you as a subject in this investigation.

In addition, if your participation in this research is for treatment or diagnostic purposes, the Hospital, or any other facility at which you are being treated, may ask you to sign a separate informed consent document for specific procedures or treatments. That informed consent may be included in the medical record of the Hospital or of that facility. Your medical record will be maintained by your treating physician or the Hospital, as appropriate, and will be subject to state and federal laws and regulations dealing with the confidentiality and privacy of medical records.

8. Contact

You may contact Dr. Sarah Frasure (212-523-3981) regarding questions about the study. You may also contact the Patient Representative (212-523-3700) regarding your rights as a research subject, including the right of immediate discontinuation of your participation in the study at any time.

9. Voluntary participation

Participation in this study is voluntary. Refusal to participate will not affect your medical care in the Emergency Department or at St Luke's Roosevelt Hospital Center.

10. Compensation

You will receive no compensation for participation in this study.

11. Questions

We are happy to answer any questions you may have about this research study, both now and in the future. You may contact Dr. Sarah Frasure at 212-523-3981.

12. Copy

You will receive a copy of this consent form.

13. Costs

There are no costs to you as a result of your involvement in this study.

14. Termination

If you become short of breath or develop chest pain while lying down for the second part of the study, which lasts approximately 3-5 minutes, we will sit you up immediately and stop the exam.

15. Withdrawal

You may withdraw from the study at any time while the investigator is performing the ultrasound examination in the Emergency Department.

PRIVACY BOARD APPROVED

SEP 19 2012

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

RESEARCH AUTHORIZATION

Patient Name: _____ **ID Number:**_____
IRB Study Number: _____12-107_____

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

You or your representative should read the information on this form before signing it. A representative of St. Luke's-Roosevelt-Hospital Center *must have filled in the answers to the questions below before providing this authorization form to you and must answer any questions you may have before you sign the form. DO NOT SIGN A BLANK FORM.*

Who will disclose, receive, and/or use the information? All of the following person(s), class(es) of persons, and/or organization(s) listed in Part A and those indicated by a checked box in Part B may disclose, use, and receive the information and they may use the information and disclose it to the other parties on this list, to you or your personal representative, or as required by law.

Part A

- This Hospital Center's research staff and medical staff
- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- The United States Food and Drug Administration and any other government agency that oversees research
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- Principal Investigator: Sarah Frasure, MD
- Study Coordinator: Sarah Frasure, MD
- Members of the Research Team and the physician fellows and data managers at St. Luke's-Roosevelt Hospital Center who are assisting the Principal Investigator on this research project.

Part B

- o All other research sites for this study, including each site's research staff and medical staff
- ☐ The following research sponsor(s):_____
- ☐ Contract Research Organization:_____
- ☐ Data Safety Monitoring Board/Clinical Events Committee
- ☐ Others (as described below):

_____

_____

Note: The name of the sponsor or the contract research organization may change through mergers, assignments or sale of assets.

What information will be used or disclosed? The appropriate boxes must be checked below and the descriptions should be in enough detail so that you (or any organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.

- ☐ The entire research record
- ☐ Any medical records held by the hospital may be used and disclosed.
- ☐ The following information:

_____

_____

_____

- ☐ HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

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) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your medical (and research-related) treatment (when applicable), and to run the business operations of the hospital.

St. Luke's-Roosevelt staff members and physicians who are performing this research will use and disclose your information only as described earlier. However, once we disclose it to others for research purposes, St. Luke's-Roosevelt cannot directly control their future uses and disclosures of it. For this reason, St. Luke's-Roosevelt has requested that the research sponsor and its agents use your information only for this research and not for other purposes. You have the right to request to review your medical records but for the duration of this study (if it is blinded) you agree to waive your right to review any aspect of the research record that would result in your knowing to which of the research groups you have been assigned.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization. If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the hospital has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. This authorization will never expire unless and until you revoke it. To revoke this authorization, please write to the Principal Investigator, Sarah Frasure MD, at St. Luke's-Roosevelt Hospital Center, 1000 10th Ave, New York, New York 10019.
You will receive a copy of this form after you have signed it.

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	Date
Print Name of Subject or Personal Representative	Address of Subject or Personal Representative
Description of Personal Representative's Authority	Telephone Number(s) of Subject or Personal Representative

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

Lung Ultrasound Heart Failure Study

Investigator:
ED Visit Date:
Study Number:

Patient Information:

- **[ ] Age:**
- **[ ] Gender:**
- **[ ] Past medical history:**
  - **[ ] CHF**
  - **[ ] Atrial fibrillation**
  - **[ ] COPD**
  - **[ ] Coronary artery disease**
  - **[ ] Pacemaker/Defibrillator**
  - **[ ] Other:**

Chief Complaint:

- **[ ] Shortness of breath**
- **[ ] Chest pain**

Additional Data:

- **[ ] Chest X ray radiology read:**
- **[ ] EKG:**
- **[ ] BNP level:**
- **[ ] Troponin level:**
- **[ ] Creatinine level:**