INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

B-lines Lung Ultrasound Guided ED Management of Acute Heart Failure
(BLUSHED-AHF)

Physician Investigator	**Peter S. Pang, MD MS**	
Institution	**Indiana University**	**Dept of Emergency Medicine**
Location	**IU Health Methodist Hospital 1701 N. Senate Blvd AG001 Indianapolis, IN 46202**	**Sidney & Lois Eskenazi Hospital 720 Eskenazi Ave, FOB 3rd flr Indianapolis, IN 46202**

You are invited to participate in a research study assessing the use of an ultrasound guided protocol to treat congestion related to acute heart failure. Despite treating acute heart failure for decades, how to best manage patients is not well known. In fact, we treat people today the same as 40 years ago. You were selected as a possible subject because your ER doctor believes you have acute heart failure, which may include symptoms such as shortness of breath, weight gain and/or leg swelling. Please read this form and ask any and all questions before agreeing to be in the study.

The study is being conducted by Peter S. Pang, MD and his research staff locally at Indiana University Health Methodist Hospital and Lois & Sydney Eskenazi Hospital, and the research staff at collaborating universities. It is funded by the National Heart, Lung, and Blood Institute, a part of the National Institute for Health.

STUDY PURPOSE

The purpose of this study is to determine if an ultrasound guided treatment protocol leads to faster resolution of congestion compared to what we usually do in the ER. The most common heart failure symptoms include difficulty breathing, weight gain, and leg swelling (edema). This ultrasound guided approach uses the same treatments ER doctors normally use. In other words, no new medications will be given to you, only those that are used every day. The difference is the use of ultrasound to help guide the treatments you receive. Ultrasound is what we use to see the baby in pregnant women. We will use the same type of ultrasound of the lungs (LUS) to guide management. LUS (lung ultrasound) does NOT use any radiation. When you have congestion, or fluid in the lungs, LUS helps us to see this fluid.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of 130 subjects who will be participating in this research across 3 universities. About 50 subjects will be enrolled at either IU Health Methodist or Eskenazi Hospital here in Indianapolis.

PROCEDURES FOR THE STUDY

Your participation in this study will include up to 6 hours in the ER, and include study visits during hospitalization, if you are admitted. Study staff will call you approximately 30 days and again at 90 days from discharge.

You will be randomized (like a flip of the coin) to either usual care or the LUS guided treatment strategy. That means 50% of the people who enroll in this study will receive the usual care provided to acute heart failure patients, meaning your care will be guided by the ER physician's assessment of your condition alone and not by the results of the LUS. The other 50% will receive LUS guided treatment, using the same types of treatment an ER physician would order but with LUS done to help guide that treatment. No matter which 50% you are assigned to, LUS will occur.

Your care will be managed in cooperation with your assigned ER physician. Study treatments may be modified to coincide or align with treatment your doctor orders for you. Your care and safety is most important and will always take precedence over the study.

How does LUS work? A plastic probe is placed on your chest in various locations to scan your lungs. Gel is placed on your skin on your chest in various places. This helps the machine to take better pictures. The gel may feel cold at first. The chest is divided into 8 zones with images taken from each zone. Trained staff will glide the probe over your skin into each of these areas. Pictures of each section are taken. These pictures will be saved and then securely sent to a professional ultrasound reader who will provide a more detailed description. There is no charge for the study related LUS procedures.

Your discharge from the ER or hospital will be determined by the physicians caring for you.

If you agree to be in the study, you will do the following things:

- You will be asked to read and sign this consent and an authorization form so we can review your medical records for the purposes of the study.
- You will answer questions regarding your demographics, symptoms, past medical history and home medications.
- You will have your blood pressure, pulse, temperature, height and weight taken daily. Your blood pressure may be checked several times over a six hour period.
- LUS will be completed by a trained staff member 3-4 times during the first 6 hours and then once a day for 7 days or until you are discharged.
- Research staff will ask the ER physician to reassess your condition every 2-4 hours during the first 6 hours.
- Research staff will collect 3 tubes of blood on the day you are admitted and again before you are discharged (about 12 ml or 2.5 teaspoon each time) to test the levels of biomarkers called NT-proBNP and hsTroponin in your blood. These tests tell us how much congestion you have as well as if you have had any injury to your heart muscle. Total blood that may be collected during the study is approximately 4-5 teaspoons or 24 ml).
- You will allow us to store the biomarker samples until they can be tested at a later time. These samples may also be used for other studies or analyses. No genetic testing will be done and your private health information and confidentially will always be protected.
- You will be asked about any new symptoms you may have developed or any concerns you may.

The following therapies may be used to treat your symptoms:
(all items may also be used if you are not in this study. In other words, there are NO experimental therapies)

- Medication called Lasix or furosemide (a diuretic or water pill) may be given to you via the IV in your arm. The dose may be repeated or increased depending on staff assessment and/or LUS.
- Medications commonly employed for treatment of heart failure, called vasodilators, may be given depending on your blood pressure status.
- Nitroglycerin may be given under your tongue, as a paste on your chest, and/or via the IV in your arm. This also is dependent on your blood pressure readings.
- Breathing devices called 'Non-invasive ventilation' (these are tight fitting masks to help your breathing) may be employed to assist your breathing. Use of these devices depends on your breathing rate and oxygen saturation (generally oxygen saturation is determined from your finger tip using a clip on device).
- These treatments may be repeated based on the LUS results and reassessments for up to 6 hours

Approximately 30 and 90 days after you are discharged staff will call you to ask you or a family member about any ER visits or re-hospitalizations that have occurred during that time. They will ask you or your family if you have been admitted to the hospital and about vital status (whether you are alive or have died).

Research staff will review your records for information that includes:

- Chest x-ray results on admission

- Electrocardiogram results on admission
- Medication records on medications you may be taking at home prior to your ER visit, medications given to you in ER and throughout your hospitalization. Medications you are to take on discharge home.
- Results of routine lab testing on admission
- Results of routine lab tests done during your hospital stay
- Vital signs taken including weight and height on admission and during your hospitalization
- Return ER visits or hospitalizations at 30 and 90 days
- Your vital status

RISKS OF TAKING PART IN THE STUDY

The major risk is the possible loss of confidentiality of your private medical information. The information collected from your medical records in paper form will be kept in locked filing cabinets. At the end of the study, your information will be stored in a secured facility until they can be legally destroyed in about 5-7 years. Information collected will be entered into a computer database without any identifiers such as your name, address, or birthdate, or date of admission. The database is password protected allowing only those staff working on the study to access it.

While there are no known serious health risks related to lung ultrasound, there is the potential risk of feeling cold or uncomfortable, as a gel is used to help generate the 'soundwaves' for ultrasound (though you can't hear anything). Blood will be drawn by experienced nurses, technicians or study staff. Whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered. Standard care using a nasal cannula or the mask for non-invasive ventilation may be uncomfortable. The medications listed above have risks or side effects which are no more than what is expected in a non-research setting. Both the doctor caring for you as well as research staff can explain those to you.

Biomarker blood samples will be stored in a secure blood storage lab and will be labeled with your assigned study number. There will be no private health information on the blood sample. The bio-storage lab personnel do not have access to the key (the list identifying what subject was assigned what number).

BENEFITS OF TAKING PART IN THE STUDY

It is reasonable to expect less frequent hospitalizations for heart failure symptoms and a longer life. However, it is also possible to experience no benefit. If the study shows that this method works well, others may benefit in the future. Even if the study shows the treatment is not effective, future patients may be spared the cost or discomfort from this treatment approach.

ALTERNATIVES TO TAKING PART IN THE STUDY

You have the option of not participating in this study. Your doctor will still provide you with usual care for your condition.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review

Board or its designees, the study sponsor, NHLBI, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), and the National Institutes of Health (NIH) etc., who may need to access your medical and/or research records.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

COSTS

Taking part in this study should not lead to added costs to you or your insurance company. You or your insurance company will be responsible for **all standard of care procedures, drugs, tests, etc., such as routine labs, diagnostic tests, medication such as vasodilators, nitrates, and furosemide ordered by the clinical physician.** You will not be responsible for these study-specific costs: the lung ultrasounds, physicals done by a research doctor, or routine labs drawn strictly for study purposes (Day 7 or discharge). However, you may be billed for an LUS if your ER physician performs one as part of their usual care outside of the study.

PAYMENT

You will receive payment for taking part in this study. You will receive a $30 gift card or a $30 check mailed to your home after completing the Index visit requirements.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

FINANCIAL INTEREST DISCLOSURE

The doctor in charge of this study has no financial interest to disclose.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Peter S. Pang, M.D. at 317-880-3800. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or 800-696-2949. After business hours, please call the main research office at 317-880–3900 and someone will get back to you as soon as possible.

In the event of an emergency, you may contact Dr. Peter S. Pang at 317-274-5000 and ask the operator to page him.

For questions about your rights as a research participant or to discuss problems, complaints, or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or 800-696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with IU Health Methodist Hospital or Sidney and Lois Eskenazi Hospital.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: 1) in the event of secondary illness, 2) adverse events, 3) lack of compliance with the study and/or study procedures such as the LUS, 4) or any reason where it is felt that it is in the best interest of the subject to be terminated from the study.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health or to your treatment; however, we will not share this information with you.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

Specimens collected from you for this research may be used to develop products which could be sold in the future. The investigator does not plan to share any profits or losses from the sale of those products with you.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records.

I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____**Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent:_____**Date**:_____