CONSENT FORM

LOCATION

SUNY Downstate/University Hospital of Brooklyn Emergency Department
Kings County Hospital Emergency Department

TITLE OF STUDY

EMERGENCY DEPARTMENT CENTRAL LINE CONFIRMATION WITH SALINE FLUSH AND BEDSIDE ECHOCARDIOGRAPHY: A PROSPECTIVE STUDY

We are asking if you want to be in a research study. This study is for people with illnesses that require placement of a central venous catheter.

What you should know about research studies:

- This consent form gives you information about the study. It tells you about the purposes, risks, and benefits of this research study.
- ***Regular care*** is based on the best-known treatment. The main goal of regular care is to help the individual patient. The main goal of ***research studies*** is to learn more so that we can help future patients. You might benefit from being in the study, but we cannot promise this.
- There may be risk to participating in this study.
- Your participation is voluntary. You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change.
- Please read this consent form carefully. Ask any questions you have before you make a decision. The study doctor will answer your questions. You may consult with your family or friends.

1) Why is this research being done?

When people come to the emergency room and are very sick, they sometimes need a large IV in a big vein to give them medications very quickly to help their heart and body. This IV is called a central line. After this large IV is placed, we want to use this IV right away to give medications as quickly as possible. We can't do that right away because we have to make sure the IV is in the right place by getting a chest xray. This may take more than 20 minutes. That can delay the sick patient getting medicine they really need. Our study will use an ultrasound that looks at the heart to see whether the IV is in the right place by injecting salt water through the IV. If it is in the right place, we can see the bubbles from the salt water on the ultrasound of the heart. This confirmation at the bedside can help save precious time.

2) Who is doing the study?

Dr. Ershad Elahi from the Department of Emergency Medicineis in charge of this study at this location. 91 people will be in the study at this location. 91people will be in the study around the country.

3) Will it cost me money to be in this study?

You will not be charged for participating in this study. All procedures, tests performed and/or drugs given to you for participating in this study are being done only for research. Therefore, you and your insurance provider will not be billed.

4) You cannot be in this study if:

You cannot consent or next of kin (a 1st degree relative, spouse, or health care proxy)to this study or if you are not getting a central line placed.

5) Pregnancy:

You are at no greater risk if you are pregnant.

6) What will happen to you if you decide to be in this study?

You are selected for this study if your doctor has already decided that you need a central line to get certain medications. The central line will be placed as it is for any patient who is need of it. After the central line is placed, saline, which is used to clear all blood from the IV tubing, will be pushed through the IV tubing. This saline will be shaken to create bubbles that we can see when we ultrasound your heart. The ultrasound does not hurt and you will only feel a little pressure and cold gel. After the ultrasound, a chest xray will also be taken, which is always taken after placing a central line.

7) What are the possible risks of being in the study?

There is no greater risk to this study than the risks already explained to you for getting a central line placed. The injected saline is the same saline you get in any IV, and it being pushed into the IV without any addition of air does not increase any risk of air in your veins that may cause stroke or heart problems. More than 0.5 milliliters per kilogram of air is needed for these adverse effects (or at least approximately 35 milliliters of air). There is no added air in the syringe with saline.

8) What are the possible benefits of being in the study?

There is no directbenefit to you for participating in the study.

9) What are your other choices?

The alternative to being in this study is to not participate.

10) If you have any questions or problems, whom can you call?

If you have any questions about this study, you can call Dr. Ershad Elahi at 347-603-4047. If you think you have been injured because of the research, you should call Dr. Ershad Elahi at 347-603-4047

If you have questions about your rights as a research subject, you can call the IRB office at (718) 270-2680, or you can contact the SUNY HSCB University Hospital Medical Director's Office at (718) 270-2401 or the Kings County Hospital Center Medical Director's Office at (718) 245-3921.

11) What information do we keep private?

In this study we will keep your personal information confidential. We will hold your identity confidential and all data will be kept in a secure, limited access location. We will not reveal your identity in any publication or presentation of the results of the study. However confidentiality cannot be guaranteed; your personal information may be disclosed if so required by the Federal Privacy law.

A 6 second ultrasound video will be recorded of your heart while we see the bubbles coming into the heart. These clips will be stored on a password protected hard drive and your name will not be associated with the video that is stored.

Federal law protects your right to privacy concerning Individually Identifiable Health Information (IIHI). There are certain things you need to know, IIHI is any information from your medical record, or obtained from this study, that can be linked to you, and that refers to your mental or health conditions in the past, the present or the future.

For this study we will create, use or report the following IIHI:

- Information from your medical records including
    - Medical Record Number
- Information obtained from this study, including
    - Age
    - Gender
    - Body Habitus
    - Reason for having central line placed
    - Chest xray findings

The researchers, Drs Ershad Elahi, Ninfa Mehta, ShahriarZehtabchi, Mike Secko, Teresa Smith, Elizabeth Rubano, Walter Valesky, Kelly Maurelus, Jennifer Ballinger, Elisa Aponte, Diane Scheer and their staff and the staff of SUNY Downstate Medical Center and Kings County Hospital Centerparticipating in the research will use your protected IIHI for this research study.

Your IIHI will be shared with the following persons or agencies for purposes related to the conduct of the research:

- The Data Safety Monitoring Board that reviews the safety of this study
- The Institutional Review Board of SUNY Downstate Medical Center, the applicable DMC and KCHC officials, and the federal Office for Human Research Protections.

We will have to use and report your health information for an indefinite period of time.

You need to know that some of the individuals or groups mentioned above are not obligated to protect the privacy of your IIHI. For example, the sponsordoes not have the same obligation to protect your IIHI under the federal privacy laws.

This information can be shared with you at the end of the study.

You can withdraw this authorization for the use or reporting of your IIHI. You have to write to us to withdraw:
Dr. Ershad Elahi
450 Clarkson Avenue
Box 1228
Brooklyn, NY 11203

If you withdraw we will stop collecting and accessing your IIHI, but we will collect and report any adverse event (bad effect) that you had in the study. Your IIHI collected before you withdraw your authorization will still be used and reported.

If you withdraw your authorization you canno longer be in the study.

12) Can your being in the study end early?

Being in this study is voluntary. You do not have to be in the study if you don't want to. You can agree to be in the study now and change your mind later. If you want to quit the study, you should talk to Dr. Ershad Elahi or one of the study staff members.

Dr. Ershad Elahi can take you out of the study without your permission. Possible reasons for this are:

-Inability to place a central line.

13) What else do you need to know?

If you agree to be in the study, we will pay you $0 for study-related expenses.

If we find out any new information that might affect your decision to stay in the study,

we will give it to you.

You might be injured by being in this study. If you are, emergency care will be available. If your study visit(s) take place at SUNY Downstate Medical Centerdoes not have a policy to pay you if are injured by being in the study.

If your study visit(s) take place at Kings County Hospital Center, New York City Health and Hospitals Corporation does not provide financial compensation for injury or illness from participation in research. Payment for medical treatment, both standard and experimental, as well as treatment of any side effects will be assumed in the usual manner by you personally or through your medical insurance; unless a Sponsor, such as a pharmaceutical or device manufacturer agrees to compensate you for treatment costs for a research related injury not covered by your insurance. However, medical care for any injury or illness resulting from patient participation is available regardless of ability to pay.

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14) Subject Consent

By signing this consent form you accept that you read this form, or had it read to you. You agree to be in the study and authorize the use and reporting of your individual identifiable health information (IIHI) as explained in this form. You will not be giving up any of your legal rights by signing this consent. We will give you a copy of this form and of DMC's and Kings County Hospital Center Notice of Privacy Practice.

_____	_____	_____
Signature of Subject (or Legal Guardian)	Date	Print name
_____	_____	_____
Signature of Next Of Kin or Healthcare Proxy *(If subject is unable to consent)*	Date	Print name
_____		
Relationship to Patient		
_____	_____	_____
Signature of Witness	Date	Print name