IRB APPROVED CONSENT FORM

JAN 25 2013

Beth Israel Medical Center ☐

St. Luke's-Roosevelt Hospital Center ☒

PERMISSION FOR PARTICIPATION OF CHILD IN RESEARCH

_____ **Resa Lewiss, MD**
Print name of subject Principal Investigator

What are baseline measurements of Inferior Vena Cava diameter in normovolemic children?

Title of Project

IRB # 11-119

Attached to this form is a full description of the study in which we are asking your child 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 and benefits to your child. The description also gives you information about other medical treatments your child may receive if you do not want your child to participate in this study.
If you have questions concerning this research project or your child's rights as a research subject, or if your child has a research-related injury, you may telephone:

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

CONSENT TO PARTICIPATE -- CHILD

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 that my child may participate in the study and take all the tests or procedures mentioned in the study description. If my child is 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 for my child to participate, and that my child can stop participating at any time. I also understand that my decision to have my child participate in or to withdraw from the study will not affect the health care my child receives, 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 parent or legal guardian date signature of witness date

_____
signature of child who assents to participate in research date

May only be used to enroll subjects until:

JAN 24 2014

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 12/24/02

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

INFORMED CONSENT
IRB # 11-119

Title: What are baseline measurements of Inferior Vena Cava diameter in normovolemic children?

1. PURPOSE.

- This is a clinical research study of the use of ultrasound, which is a painless, noninvasive tool, to measure a patient's hydration status by measuring the width of the inferior vena cava (IVC), a large vessel that enters the heart.
- You have been asked to take part in this study because you are a healthy individual in the emergency department and are assumed to be clinically well hydrated. By having a better understanding of what a healthy IVC looks like in a well hydrated child, we hope to be able to develop the ability to identify what an unhealthy or dehydrated IVC looks like in the future.
- This study is measuring baseline widths of the inferior vena cava (IVC) in healthy individuals in order to see what a normal, healthy IVC width looks like.
- You will be one (1) of about 80 patients who will be participating in this study. The study will be conducted in the Emergency Department at either St. Luke's Hospital or St. Luke's Roosevelt Hospital.
- Ultrasound Tests:
    - For the experimental portion of our study, we will be using an ultrasound machine to measure your inferior vena cava (IVC). For the ultrasound measurement, you will be lying down on your back on your bed. A gel will be placed on the ultrasound probe, which will then be placed gently on the middle of your chest, just under the ribcage. The gel may feel cold but it should not be painful. As measurements of the IVC are being done, you may feel some pressure from the probe but it should not be painful.
    - Multiple10-second video clips as well as still images will be recorded over several minutes as we look for the best views of your IVC. These images will not be labeled with your name or your medical record number. You will be given a study subject number if you wish to enroll in this study that is independent from your medical record.
    - These video clip recordings will be saved in a computer database under your study subject number and may be used in the future as a teaching tool to other students who are not members of the research staff.
- No additional blood or urine tests will be drawn for the purposes of this study.
- No additional medications will be given to you for the purposes of this study.
- The attending physician who is directly caring for you will not know the result of the ultrasound studies and will continue his/her management based on current treatment methods.

2. DURATION

- Your participation in this study, should you choose to enroll, will last only as long as it takes to record the ultrasound images of your IVC, which will take approximately 10-15 minutes.

3. RISKS

- Ultrasound is a painless and non-invasive tool that can be used to look inside the body. There are no known risks or side effects associated with this device.
- A possible discomfort associated with ultrasound is that the gel may feel cold. During the ultrasound measurements, there may also be some slight pressure placed on the chest/abdomen but this should not be painful.
- All necessary measures will be taken to secure your private information, however there is always a risk of breach of confidentiality. A breach of confidentiality is when someone sees your health information without your permission.

4. BENEFITS

- You will not benefit from being in this research study. However the information learned from this study may, in the future, benefit other people.

5. ALTERNATIVES

- You may choose not to participate in this study.

6. 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.
- If you are participating in a multi-site research study, your information may also be shared, to the extent necessary, with researchers at associated sites for purposes such as data analysis. 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, may inspect records identifying you as a subject in this investigation.

SLRH IRB APPROVED CONSENT FORM
APPROVED FROM: 1/25/2013
JAN 24 2014
IRB# 11-119
EXPIRES ON DATE ABOVE

7. CONTACT

- If any questions arise related to this research project, you may call Dr. Resa Lewiss at (212) 523-3981. If you have questions regarding your rights as a research subject, you may call St. Luke's Hospital Patient Representative (212-523-3700).

8. VOLUNTARY PARTICIPATION

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may stop your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Informed Consent Signature Page

The following is a list of items that have been discussed with you about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate.

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- About any costs and payments.
- I can discontinue participating in the study at any time without penalty.
- Other options.
- My name will not appear on interview or other data collection forms.
- All written and published information will be reported as group data with no reference to individual study names.
- If there is a schedule explaining how the study medicines are to be taken, I will be given the time schedule.
- I have been given the name of the research study doctor and others to contact.
- I have the right to ask any questions.
- I have received a copy of this consent form to keep for my own personal records.

I have read the information above and it has been discussed with me. I agree to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Guardian or Family Member (when applicable)	Signature of Guardian or Family Member (when applicable)	Date
Printed Name of Individual Conducting Informed Consent Process	Signature of Individual Conducting Informed Consent Process	Date

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

CHILD ASSENT FORM
IRB # 11-119

Title: What are baseline measurements of Inferior Vena Cava diameter in normovolemic children?

1. Purpose (Why are you here?)
We want to do a study to see how the use of an ultrasound, a painless tool, to measure the amount of blood in your body by measuring the width of a large vein that enters your heart.

2. Procedures (What will happen?)
You will undergo an ultrasound study. For this study, you will be placed lying down on the bed. A gel will be placed on the ultrasound probe, which will then be placed gently on the middle of your chest, just under the ribcage. We will record a few 10-second video clips of the images we see through the ultrasound.

3. Risks (Will it hurt?)
No. The ultrasound is safe and does not hurt. The gel may feel cold but it should not be painful. As measurements of the IVC are being done, you may feel some pressure from the probe but it should not be painful.

4. Benefits (How may it help me?)
Being in this research study will not help you; but what we learn from this study may help others in the future.

5. Alternative Procedures (Can you say ``No"?)
Yes. You do not have to do the ultrasound if you do not want to. You can stop at any time you want.

You have been told about the ultrasound.
You have been told what you have to do for the ultrasound.
You have been told that you do not have to do this ultrasound if you do not want to.
You have also been told that you can stop the ultrasound after you start, if you want to.

_____
Printed Name of Child

_____ _____
Signature of Child Date

_____
Printed Name of Individual Conducting Informed Consent Process

_____ _____
Signature of Individual Conducting Informed Consent Process Date

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

RESEARCH AUTHORIZATION

What are baseline measurements of Inferior Vena Cava diameter in normovolemic children?

Patient Name: _____ **ID Number:**_____
IRB Study Number: ___**11-119**_____

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: Resa Lewiss, MD_____
- Study Coordinator: Resa Lewiss, 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.

PRIVACY BOARD APPROVED

JAN 25 2013

Part B

- o All other research sites for this study, including each site's research staff and medical staff
- ❑ The following research sponsor(s): None
- ❑ Contract Research Organization: None
- ❑ 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.

x 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, __Resa Lewiss, MD____ , at St. Luke's-Roosevelt Hospital Center, ___**1111 Amsterdam Avenue, Department of Emergency Medicine**_____, New York, New York 10025_____.
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.