St. Luke's-Roosevelt Hospital Center
Institute for Health Sciences Institutional Review Board
432 West 58"' Street, Room 207, New York NY 10019
Telephone (212) 523-4368, 4370, 6296 Fax (212) 523-7442

MEMO - Approval of Protocol by Expedited Review

To: Jennifer Martin, MD

From: Theodore Bania, MD, IRB Co-Chair
Charles W. Paley, MD, Co-Chair

FILE COPY

Date: December 12, 2011

IRB#: 11-138

Title: Does bedside ultrasound training teach fourth year medical students to accurately measure the inferior vena cava diameter?

The Institutional Review Board reviewed and approved the above-cited protocol by expedited review. This project is eligible for expedited review because it is research involving no more than minimal risk, and is research involving the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Additionally, the Privacy Board has reviewed and approved the Research Authorization forms to be given to participants enrolled in the above-cited research project. Your stamped IRB/Privacy Board approved Authorization and Informed Consent Forms are enclosed.

You may now begin the proposed research. This approval will be reflected in the minutes of the IRB meeting of December 21, 2011. Please note that for all sponsored research, approval by the Grants Office must be obtained in addition to IRB approval prior to starting the research.

The IRB has approved the following individuals to be responsible for conducting the research:

1) Jennifer Martin, MD
2) Turan Saul, MD
3) Resa Lewiss, MD
4) Lorraine Ng, MD

Further changes in the protocol may not be made without IRB review and approval. The only exception would be if these changes were necessary to eliminate apparent immediate hazards to the human subject. Any serious unanticipated adverse events or unexpected reactions, including death, loss of limb, need for operation, etc., should be reported by the Principal Investigator in writing to the IRB within 48 hours of occurrence or receipt of report of occurrence.

Your study will be due for continuing review by **December 11, 2012**. You will receive a notice of reminder one month prior to that time.

FDA regulations require that you notify the IRB when your study is completed.

All correspondence concerning this matter should be submitted electronically to irbSubmit@chpnet.org.
If you should have any questions, please contact the IRB Coordinator at 523-4368, 4370 or 6496.

IRB APPROVED
CONSENT FORM

DEC 1 2 2011

St. Luke's-Roosevelt Hospital Center

CONSENT FOR PARTICIPATION IN RESEARCH

_____ Jennifer A Martin, MD
Print name of subject Principal Investigator

Does Bedside Ultrasound Training Teach Fourth Year Medical Students to Accurately Measure Inferior Vena Cava (IVC) Diameter?
Title of Project

IRB # 11-138

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: 917 723-2669

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

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

May only be used to enroll subjects until:

DEC 1 1 2012

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

REV 4/19/07

Medical Student Consent Form

Informed Consent to Participate in Research Study Entitled: Does bedside ultrasound training teach fourth year medical students to accurately measure the inferior vena cava (IVC) diameter?

Purpose: The purpose of this study is to assess medical student ability to accurately assess the diameter of the inferior vena cava as a non-invasive measure of intravascular status after viewing a brief instructional video.

Procedures: If you choose to participate, you will view this video, then perform ultrasounds on three patients in the emergency department using the technique covered in the video. You will also interpret the diameter and intravascular volume status of the patient who's IVC you ultrasound. You may choose to complete all your ultrasounds in one day or use your entire month rotation to complete the required three scans.

This is a study of fourth year medical students rotating in the emergency departments at the St. Luke's Roosevelt Hospital Centers.

The study is being conducted by Jennifer Martin, MD, Resa Lewiss MD, Registered Diagnostic Medical Sonographer (RDMS), and Turandot Saul MD, RDMS.

Benefits: Expected benefits of this research are possible addition ultrasound education to medical school curricula in the pre clinical years.

Duration: It will take approximately 20 minutes to view the instructional video and learn basic machine use. The time to perform IVC ultrasounds will vary. Finally the time to complete the data collection sheet will be approximately 5-10 minutes. You may choose to complete all your studies in one day, or take your entire month rotation to complete the required studies.

Risks: There are no foreseeable risks or discomfort expected of participants.

Alternatives: You may choose not to participate in this study.

Contact: If you have any questions about your rights the SLRHC Patient Representative at 212-523-3700.

Voluntary Participation: Participation in this study is entirely voluntary. Voluntary participation also means:

- You need not answer any questions you consider inappropriate
- You may stop participating at any point
- You may decline to participate in the hands on time using ultrasound to assess IVC diameter
- If you decline to participate, you may return the blank data collection sheet or destroy it
- If you decline to participate, it will in way affect your grading, evaluation or standing within the Department of Emergency Medicine at SLRHC or your medical school.

Compensation: There is no monetary compensation for participation in this study.

Confidentiality: The data collection forms are completely anonymous and confidential. You will be assigned a random number that will be used to review the ultrasound images you obtain. Do not share this number with anyone. To ensure anonymity, please do not put your name or any other personal identifiers on the survey.

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, 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.

Questions: You are free to ask any questions you have prior to your agreement to participate in this study. And, if in the future you think of additional questions, please contact the principal investigator Jennifer Martin at 917-723-2669.

Copy: You will receive a copy of this informed consent should you choose to participate in the study.

Termination: Your participation in the study may be terminated by the investigators if they are unable to interpret the images you obtain.

Cost to Subject: There are no costs to the subjects.

Withdrawal: You are free to withdraw your participation in this study at any time. If you choose to do so, it will in no way affect your course grade, evaluation, standing within the Department of Emergency Medicine at SLRC or your medical school.

Signature of Participant: _____ Date: _____

Revised: 11/4/11

PRIVACY BOARD APPROVED

DEC 12 2011

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

RESEARCH AUTHORIZATION

Patient Name: _____ **ID Number:**_____
IRB Study Number: _____**11-138**_____

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: Jennifer A.Martin,, MD
- Study Coordinator: N/A
- 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

- ☐ 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):

Co Investigators, Turan Saul, MD RDMS, Resa Lewiss, MD RDMS, Lorraine Ng, MD

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:

Your ultrasound images

- ☐ 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, _____ , at St. Luke's-Roosevelt Hospital Center, _____, New York, New York 100_____.
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.

IRB APPROVED
CONSENT FORM

DEC 12 2011

St. Luke's-Roosevelt Hospital Center

CONSENT FOR PARTICIPATION IN RESEARCH

_____ Jennifer A. Martin, MD.
Print name of subject Principal Investigator

Does Bedside Ultrasound Training Teach Fourth Year Medical Students to Accurately Measure Inferior Vena Cava (IVC) Diameter?
Title of Project

IRB # 11-138

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: 917-723-2669

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

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

May only be used to enroll subjects until:

DEC 11 2012

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

REV 4/19/07

Patient Undergoing Ultrasound Consent Form

Informed Consent to Participate in Research Study Entitled: Does bedside ultrasound training teach fourth year medical students to accurately measure the inferior vena cava (IVC) diameter?

This is a study of fourth year medical students rotating in the emergency departments at the St. Luke's Roosevelt Hospital Centers.

The study is being conducted by Jennifer Martin, MD, Resa Lewiss MD, Registered Diagnostic Medical Sonographer (RDMS), and Turandot Saul MD, RDMS.

Purpose: The purpose of this study is to assess medical student ability to accurately assess the diameter of the inferior vena cava as a non-invasive measure of intravascular status after viewing a brief instructional video.

Procedures: Students will view an instructional video, then perform ultrasounds on patients in the emergency department using the technique covered in the video. The students will also interpret the diameter and intravascular volume status of the patient who's IVC you ultrasound.

If you choose to participate, you will serve as a model, and the medical student will perform an ultrasound of your IVC. This will require that the student place an ultrasound probe on your upper abdomen to visualize your IVC. Then, several measurements will be obtained. This is the extent of your role in the study.

Benefits: Expected benefits of this research are possible addition ultrasound education to medical school curricula in the pre clinical years.

Duration: The time to perform IVC ultrasounds will vary, with most taking between 5-10minutes total.

Risks: There are no foreseeable risks to the patient. However, during the ultrasound, the patient may experience mild abdominal discomfort as the probe touches the abdomen.

Alternatives: You may choose not to participate in this study.

Contact: If you have any questions about your rights the SLRHC Patient Representative at 212-523-3700.

Voluntary Participation: Participation in this study is entirely voluntary. Voluntary participation also means:

- You may stop participating at any point

Compensation: There is no monetary compensation for participation in this study.

Confidentiality: The data collection forms are completely anonymous and confidential. Your ultrasound images will only be identified by your medical record number.

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, 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.

***Questions*:** You are free to ask any questions you have prior to your agreement to participate in this study. And, if in the future you think of additional questions, please contact the principal investigator Jennifer Martin at 917-723-2669.

Copy: You will receive a copy of this informed consent should you choose to participate in the study. You will not receive a copy of the ultrasound performed today.

Termination: Your participation in the study may be terminated by the investigators

Cost to Subject: There are no costs to the subjects.

Withdrawal: You are free to withdraw your participation in this study at any time. If you choose to do so, it will in no way affect your treatment in the emergency department.

Signature of Participant: _____ Date: _____

Revised: 11/4/11

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

RESEARCH AUTHORIZATION

Patient Name: _____ **ID Number:**_____
IRB Study Number: _____**11-138**_____

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: Jennifer A.Martin,, MD
- Study Coordinator: N/A
- 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

DEC 12 2011

Part B

- ❑ 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):

Co Investigators, Turan Saul, MD RDMS, Resa Lewiss, MD RDMS, Lorraine Ng, MD

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:

Your ultrasound images

- ❑ 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, _____ , at St. Luke's-Roosevelt Hospital Center, _____, New York, New York 100_____.
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.