

# Saint Luke's Health System

## Consent for Research: Study Group

**Project Title:** Validation of a non-invasive cardiac monitor (NICOM) in pregnant women with structural heart disease

**Principal Investigator:** Investigator-Initiated

**Principal Investigator:** Karen Florio, DO

---

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose, and the risks and possible benefits of participating in the study. Please take time to review this information carefully. After you have finished, you may talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation. If you decide to take part in the study, you will be asked to sign this form.

### **Purpose**

The purpose of this study is to establish the usefulness of the "NICOM" (non-invasive cardiac output monitor) in women with heart disease in labor. A NICOM is a machine used to measure fluids. This study will utilize both echocardiograms (ultrasound imaging of the heart) and the NICOM to determine how hard your heart is working throughout the pregnancy and postpartum period. An echocardiogram is used in pregnancy for women who have heart problems or heart disease (such as shortness of breath or chest pain) to determine the heart function. It is safe and is used as the gold standard tool for evaluating the heart. The NICOM machine is a FDA approved device that also measures heart function in the non-pregnant population and is used in the ICU setting nationwide. It is also safe and has been approved for women who are pregnant. What we would like to determine during this study is if this NICOM machine is accurate throughout gestation by comparing it to an echocardiogram measurement of heart function.

The NICOM machine is an easy-to-use, quick assessment of heart function. It consists of four sticky pads that are placed on your chest to measure cardiovascular function. It will only be applied for 15 minutes at each visit and is explained in detail below.

This study will have two groups:

**Study Group:** Any woman with known heart disease who presents for care in the first trimester with a single baby pregnancy. If you agree to participate in the study, you will be assigned to this group.

**Control Group:** Any woman with no known heart disease who presents for care in the first trimester with a single baby pregnancy.

100 subjects are expected to participate in this research study:

- 50 for the study group
- 50 for the control group

## Study Procedures

### What will happen to me in this study?

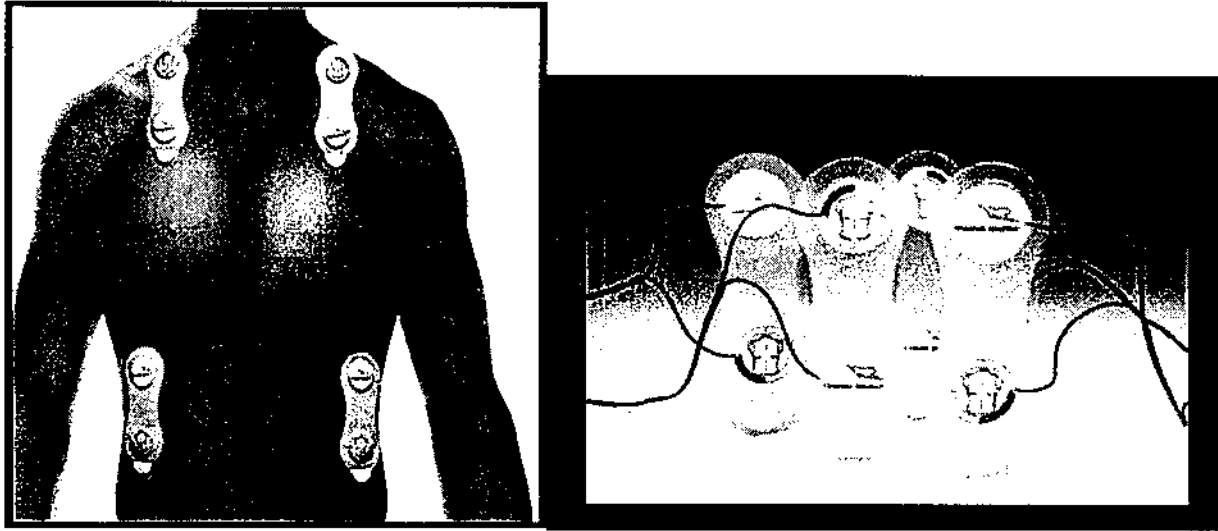
#### Initial Exam

One of the study physicians or nurses will tell you about the study and answer your questions before asking you to sign this consent form. Once you have signed the consent form, we will review your medical records. We will collect information about your demographics (medical history, age, weight, pregnancy history, family history, medications, diagnostic tests). The data we collect will be entered into a confidential database. The data will not have any information that can identify you specifically. Your data will be identified by a code (such as a patient number and a number for your hospital). The key to the specific study code will be secured at St. Luke's Hospital with only the study team having access to this code.

The first visit will include both an echocardiogram (an ultrasound of your heart) and placement of the NICOM leads and measurement. It is normal and the standard of care for women with heart disease to have an echocardiogram each trimester, and some centers order them more frequently depending on your condition. The echocardiograms will take place in the cardiovascular imaging department, down the hall from the PEET center. You will be asked to undress from the waist up, and ultrasonic (water-based) gel will be applied to your chest to allow pictures to be taken of your heart. This test should last anywhere between 30 minutes to 45 minutes.

Following that procedure, you will be asked to present to the Maternal-Fetal Medicine department for the NICOM test. The NICOM leads (4 sticky pads similar to what is placed during an EKG test) will be placed on your chest and left for 15 minutes while the machine collects information about your heart. See picture below.

Lastly, you will be asked to give blood for a test called a BNP (this is the same type of blood draw you would have at your first prenatal visit). This will take place in the laboratory at Saint Luke's Hospital on the Plaza. This is a routine standard of care blood draw and will be billed through your insurance as normal.



#### **Follow-up Exams:**

The same procedures (echocardiogram followed by the NICOM placement and BNP blood draw) will be done in the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters at your OB visits. The echocardiogram and NICOM tests will be performed when you present to the labor suite for labor. Dr. Florio will be contacted and she will order another echocardiogram. The echocardiogram machine will be taken to the labor floor and you will have your echo at the bedside after you are admitted. Immediately following, the NICOM machine will be wheeled up to the labor suite and again, for 15 minutes, the NICOM leads will be placed and data will be collected. Once you have delivered, we would ask that you have one more echocardiogram (in the cardiovascular imaging center) and one more NICOM placement before you are discharged home. This can happen any time before discharge within 1 day of delivery).

We will continue to follow you during your pregnancy and immediate post-delivery care. We will collect data from your medical record on any changes to your medical history, new medications you may be using, diagnostic tests and any new complications that may have occurred since your last visit.

#### **How much of my time will be needed to take part in this study?**

Study group: After each of your normally scheduled echocardiograms, the NICOM measurements will be performed and last approximately 15 minutes beyond the normal length of appointment. Measurements taken in hospital will not extend normal hospital stay.

#### **When will my participation in the study be over?**

Your participation will be over after your hospitalization for delivery.

#### **Risks**

The risks of taking part in this study are minimal. The known or expected risks are:

- Loss of confidentiality: We will do everything in our control to protect your medical records just as we would if you were not part of the study. You will be identified in the study only by a patient number, and not by name or birthdate. Your data will be collected and stored confidentially by hospital personnel who are familiar with privacy rules and regulations.

- **Physical risk:** The physical risks to both groups include discomfort during the echocardiogram (i.e. probe pressure), allergic reactions to conductance gel, and allergic reaction to adhesive (on the NICOM electrodes). A blood draw for the labs is part of routine clinical care for the study group and can be combined with routine lab draws each trimester, with small risks of pain and bleeding during the procedure. The NICOM machine has been previously used in pregnant women and there are no known risks to you or your fetus.

As with any research study, there may be additional risks that are unknown or unexpected.

### **Benefits**

**Study group:** The benefit to the study group may be in detecting complications that may arise that otherwise may not warrant an echocardiogram (i.e. early signs of heart failure).

Other patients with heart disease in pregnancy may benefit in the future by what the researchers learn from this study.

### **Alternative to Study Participation**

This is a voluntary study. Participation in this study does not affect your doctor's recommendations for treatment of your condition. Declining to participate in this study will not affect your doctor's recommendations for treatment of your condition.

### **Financial Information**

We will be providing \$10 gas cards for participating in this study which you will receive at the end of your participation.

There are no direct costs to participate in this study. Payment for NICOM measurements for all study subjects will be handled through the study funds provided by Herbert Vincent Jones Foundation, the Run for the Roses Campaign, and Saint Luke's Foundation.

**Study Group:** Echocardiograms and labs will be billed to insurance as per normal routine care (same if in study or not in study). However, the intrapartum echocardiogram is not routine and will be paid for by the study funds. In the event your disease does not qualify you for a postpartum echocardiogram, the study funds will also pay for that test. You will not be expected to pay any additional fees outside of routine medical care/fees (that you would normally incur if you were not part of this study).

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. In no way does signing this consent form waive your legal rights nor does it relieve the Study personnel Sponsor or involved institutions from their legal and professional responsibilities.

To help avoid injury, it is very important for you to follow all study directions.

### **Confidentiality**

Study records will be kept in a separate data file that does not include names or other information that is likely to allow someone other than the researchers to link the information to you. Your data will be accessed and collected by hospital personnel who are familiar with privacy rules and regulations.

### **Privacy Protected Health Information**

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called The Health Insurance Portability & Accountability Act (HIPAA). By signing this consent form, you are giving permission for Saint Luke's Hospital System to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. Your medical records at Saint Luke's Hospital System may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at Saint Luke's Hospital System by Karen Florio, DO, members of the research team, Saint Luke's Hospital System Medical Record Department, the officials at Saint Luke's Hospital System who oversee research, including members of the Saint Luke's Institutional Review Board and other committees and offices that review and monitor research studies.

By signing this form, you are giving Karen Florio, DO and the research team permission to share information about you with persons or groups outside Saint Luke's Hospital System. Your information will be shared with the Saint Luke's Foundation, the monitoring company that inspects study data, the laboratory that processes study lab sample, other business partners of the sponsor who help with the study's data, the U.S. Food and Drug Administration (FDA), and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the NICOM].

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside Saint Luke's Hospital System disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely. Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. However, you have the right to change your mind at any time and revoke your authorization. To revoke your permission, you must do so in writing by sending a letter to Karen Florio, DO at 4401 Wornall Road, Kansas City, MO 64111.

While you are participating in this study, you may see and copy any study information that is placed in your Saint Luke's Hospital System medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

### **Summary of your rights as a participant in a research study**

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may

withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risk or benefit associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at Saint Luke's Health System (SLHS) or elsewhere; however, SLHS has no plans to provide free care or compensation for lost wages.

**Disclosure of your study records**

Every effort will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The Saint Luke's Health System Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

The researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

**Contact Information**

\_\_\_\_\_ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator (Dr. Florio) can also be contacted at 816-251-5717 if you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the Saint Luke's Health System Institutional Review Board at 816-932-3361. You may also write the Saint Luke's Health System Institutional Review Board at 4401 Wornall Road, Kansas City, Missouri, 64111. The contact information for the PI is as follows: Karen L Florio DO, 4401 Wornall Rd, Peet Center, Kansas City MO 64111. Email: kflorio@saintlukeskc.org

**Signatures**

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

APPROVED  
Saint Luke's Hospital IRB  
IRB # 18-062  
Approved date: 07/05/2018  
Expiration date: 06/11/2019

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Person obtaining informed consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining informed consent