UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Evaluation of Novel Point of Care Coagulation System in Pregnant Women

Study No.: HP-00084317

Principal Investigator: Bhavani Kodali MD, Phone: 410-328-4229

Sponsor: Hemosonics LLC

CONCISE SUMMARY:

- The purpose of this study is to determine whether the Quantra point of care coagulation system can hasten clinician management for patients with obstetric hemorrhage. Participants in this study are being asked to provide a blood sample of 21.6ml (1.5 tablespoons) and it is taken from an existing line placed into a small vein in your wrist, as part of your normal obstetric care. The risks associated with your participation are related to the blood draw and loss of confidentiality. Sterile and careful blood drawing techniques will be used to minimize potential infections, and any waste of blood. Additionally in order to minimize the potential of loss of confidentiality data will be stored in a secure location such as a locked office and or in a password protected database. If you are interested in considering joining the study, please continue reading.

PURPOSE OF STUDY

You are being asked to consider taking part in this research study because you are pregnant and we are evaluating a new point of care Quantra Hemostasis Analyzer system (Approved by Food Drug Administration) to rapidly assess how blood clots in pregnant women. We plan to enroll 20 subjects on this study. Each participant will provide a single blood sample of 21.6mL (1.5 tablespoons). The blood will be taken by using sterile and careful blood drawing techniques to minimize potential infections, and any waste of blood.

PROCEDURES

If you agree to be in this study, you will sign this consent form before any study-related procedures take place. The study procedures for which you are consenting are as follows:

1. Study team will ask the nurse to draw 21.6mL of blood (1.5 tablespoons) while placing a routine cannula into your vein.

2. The specimens will be analyzed using the new point of care Quantra Hemostasis Analyzer system.

The doctor or study staff will record some general information about your medical history including:

- Your Name and MRN

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you choose to join this study, you will only be responsible to review and sign this consent form, ask us any questions you have about the study, and agree to allow us to collect medical information and blood.

POTENTIAL RISKS/DISCOMFORTS:

Blood drawing will be conducted via existing vein lines and so you will not need to have additional needle sticks if you join the study. There is a small risk of introducing infection or causing anemia when blood is drawn. Sterile and careful blood drawing techniques will be used to minimize potential infections, and any waste of blood or hemorrhage (bleeding).

Additionally, there is the risk of loss of confidentiality. However, we follow several measures to protect your medical data by storing in a secure location, such as a locked office and locked cabinet, and your electronic data will be password protected.

POTENTIAL BENEFITS

You will not benefit directly from your participation in this study.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected

COSTS TO PARTICIPANTS

It will not cost you anything to take part in this study. You and or your insurance company will be responsible for costs associated with your labor and delivery.

PAYMENT TO PARTICIPANTS

You will not get any money for participating in this study. By agreeing to be in this study, you are donating your blood samples and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments

CONFIDENTIALITY AND ACCESS TO RECORDS

- Confidential information will be collected about you for this study. This information will include demographic information (such as age and sex), information about your medical history, and information about your clinical course during your hospitalization.
- These data will not be shared with anyone not affiliated with this study. Once the study is completed all personally identifying information will be removed from the data collection.
- Study records can be reviewed by federal agencies or the IRB at the University of Maryland.
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.
- If necessary, the monitors, auditors, other representatives of the sponsor, the IRB, the Food and Drug Administration can be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential.
- Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Bhavani Kodali, phone number 410-328-4229.

There are no adverse consequences of a participant's decision to withdraw from the study. A written request to withdraw is not required, but a study investigator must be informed your decision to withdraw. If important new findings are developed during the study that may affect your willingness to continue, you will be informed.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, these data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include the investigator feels that the patient can no longer fully comply with requirements of the study or if any of the study procedures would not be in the best interest of the patient.
The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS
The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent
Signature

Date:_____