RESEARCH SUBJECT CONSENT FORM

Title: A Clinical Study to Evaluate the Safety and Accuracy of the Saranas Early Bird™ Bleed Monitoring System for the Detection of Endovascular Procedure Related Bleeding Events

Protocol No.: PVP004

Protocol Issue Date: May 4, 2018

Sponsor: Saranas, Inc.

Investigator:

Daytime Phone Number:

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to test if the Saranas Early Bird Bleed Monitoring System (EBBMS) can detect whether bleeding occurs during a procedure being done inside your one of your blood vessels, and if bleeding occurs, how much bleeding occurs. About 100 subjects will take part in this research. You have been chosen because you need a procedure that requires a large catheter to be inserted into a large blood vessel in your leg, such as trans-femoral transcatheter aortic valve replacement (TAVR) procedure or other procedure.

How long will I be in this research?

We expect that your taking part in this research will last 1 day.

What happens to me if I agree to take part in this research?

If you agree to take part in this research, the procedure that your doctor has recommended you have will be performed in the same way and at the same place that it would have been performed. The difference will be that the EBBMS, which is like a catheter-introducing device, will also be inserted into one of your blood vessels. The same blood vessel may be used for your procedure, or the doctor may choose to put the EBBMS into a different one. The doctor may also choose to use the EBBMS device for your procedure instead of the catheter-introducing device he would otherwise have used.

The EBBMS is an investigational device, which means that it has not been approved by the Food and Drug Administration (FDA).

Below is a description of what will happen if you decide to take part in this research study.

Screening

You will be asked to sign this consent form and asked to answer some questions about yourself. Up to 90 days before your procedure you will also have a CT scan that may be performed with dye to make it easy to see your blood vessels. Up to 14 days before your procedure you will

have a physical exam, your medical history and medications will be recorded and you will have about 2 teaspoons of blood drawn for laboratory tests. If you qualify for the study, you will be scheduled to return in 1-14 days for your procedure.

Day of Your Procedure

You will come to the clinic for your procedure. You will have about 2 teaspoons of blood drawn to test your blood. Your procedure will be performed. During the procedure, the EBBMS will be inserted into a blood vessel and used to check for any bleeding inside your body in the area where your procedure is being performed. During the procedure, about half a teaspoon of blood will be drawn to check your clotting.

After Your Procedure

After your procedure has been completed you will have another CT scan (without dye) to check if there was any bleeding. You will have another 2½ teaspoons of blood drawn to test your blood. The EBBMS may stay in for up to 8 hours after your procedure has been finished to continue watching for bleeding; then it will be removed. Before you are discharged, you will have another blood draw of about 2 teaspoons, and then you will be discharged according to the clinic's usual procedures.

Only the use of the EBBMS is experimental. All other tests and procedures are a normal part of these types of procedures.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Answer any questions truthfully, including questions about your medications and medical history
- Tell us if you are pregnant

Could being in this research hurt me?

Possible risks and discomforts from the EBBMS are not expected to be much different from those of having these types of procedures done inside their blood vessels without the EBBMS. However, there may be additional risks such as:

- Blood loss, bleeding or bruising. You will recover from this in a few days.
- Blockage of a blood vessel (small or large) with temporary or permanent lack of blood to the tissues.
- Infection or scarring. Any infection will be treated with antibiotics and should go away in a week or two. Scarring could be permanent.
- Damage to the blood vessel.

- There is a risk that the EBBMS may not detect an internal bleed. However, any bleeding will be detected by the CT scan and/or blood test.
- There is a risk of improper use of the device.
- In addition to these risks, taking part in this research may harm you in unknown ways.
- Taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

The doctor will do everything possible to make the risks as small as possible, by checking for bleeding with laboratory assessments and a CT scan, and by undergoing training in using the EBBMS.

Will it cost me money to take part in this research?

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include early detection of bleeding during your procedure, so that the doctor can treat this before you lose a large amount of blood. There will be no benefits to you after this research has ended. Possible benefits to others in the future may be the availability of a device to monitor patients' bleeding during procedures in a blood vessel that require a large catheter to be inserted into an artery in their leg.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research
- The Contract Research Organization (CRO) assisting with conduct of this study, Proxima Clinical Research, Inc.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointment

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team. There are no consequences to not taking part in the research.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date