[redacted]

RESEARCH SUBJECT CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: Prospective Feasibility Study Evaluating EchoMark LP Placement and EchoSure Measurements for Subjects Requiring Arteriovenous Fistulae

PROTOCOL NO.: IDE-F1-2021 [redacted]

SPONSOR: Sonavex Inc.

[redacted]

INVESTIGATOR: [redacted]

STUDY-RELATED PHONE NUMBER(S): [redacted]

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last up to 52 weeks. Your follow-up visits will conclude at the 12-month follow-up visit.

[redacted]

Why is this research being done?

The purpose of this research is to evaluate the feasibility and safety of the EchoMark LP and the EchoSure diagnostic ultrasound system for assessing Arteriovenous (AV) fistula (a created connection between an artery and a vein) blood flow, diameter, and depth. The information collected from the EchoSure ultrasound system will be compared to information gathered using standard ultrasound (Duplex ultrasound). Your doctor will not use EchoSure information to make decisions about your care during this study.

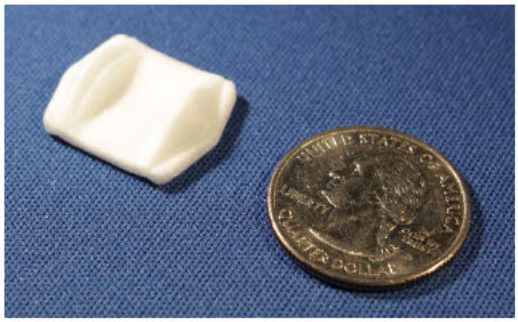

Figure 1 Photo of EchoMark LP next to a US Quarter for scale.

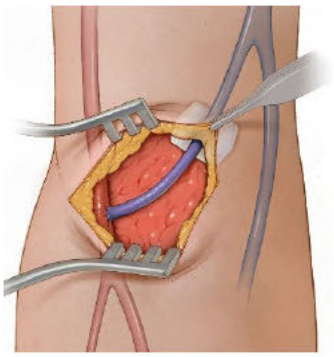

Figure 2 EchoMark LP placement near fistula

The study devices, EchoMark LP and EchoSure, are manufactured by Sonavex, Inc., which is a company based in the United States. The EchoMark LP is a small device that is implanted (inserted) in the soft tissue near the site where the fistula is created. The device can be easily detected by EchoSure, the ultrasound equipment, which can provide measurements and information about blood flow and vessel diameter and depth. At the end of the study, the EchoMarkLP device will not be removed. It is made of material that will break down and eventually dissolve. The images above show the EchoMark LP device next to a quarter for scale and where the EchoMark LP will be placed near the fistula during your surgery.

The EchoMark LP is approved by the Food and Drug Administration (FDA) for radiographic marking of sites in soft tissue and the EchoSure diagnostic ultrasound system and its transducer (device that converts one form of energy into a readable signal) are intended for use in clinical examinations of blood vessels that are marked with an EchoMark or EchoMark LP implant. The system provides measurements and information about blood flow.

The EchoMark LP and EchoSure diagnostic ultrasound system are investigational in this study, which means that it is not approved by the FDA for use in evaluating AV fistulae.

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

If you decide to take part in this research study, the procedure to create your AV fistula will occur as normal with your physician's standard surgical technique. After your AV fistula is created, your surgeon will dissect tissue to create a pocket for the EchoMark to be placed in. Next your vein to be placed directly through the EchoMark channel and the EchoMark will be sutured in placed.

[redacted]

During the recovery process, you will be required to come to the doctor's office for follow-up visits. These visits will include a physical exam, medical history review including the most recent laboratory results and cannulation (a plastic tube placed into your vein) attempts/dialysis, duplex scan (to evaluate how blood flows through arteries and veins), and EchoSure scan of your fistula. The follow-up visits will occur at 15, 30, 60, 90, 120, 150, 180, and 365 days after surgery.

Could being in this research hurt me?

The study involves the creation of an AV fistula, therefore the risks of participating in this research include the risks associated with AV fistula creation which may include bruising, numbness, tingling and/or coolness in the extremity, thrombosis (blood clot), stenosis (narrowing of blood vessel), failure to mature, additional interventions, venous hypertension (elevated blood pressure inside your veins) , swelling, irritation or pain, bleeding/hemorrhage, hematoma (bruising), seroma (fluid collection), wound problem, fever, steal syndrome (reduced blood flow), ischemia (inadequate blood supply to parts of body), embolism (blocked artery), infection, increased risk of congestive heart failure (condition where heart does not pump sufficient blood), nerve damage, vessel damage, pseudoaneurysm (injury of blood vessel that results in blood leaking to surrounding area), compartment syndrome (a painful condition that occurs when pressure builds in an area of the body, heart problems such as arrhythmias (irregular heart rate), burns, problems due to sedation or anesthesia, sepsis (body's response to infection), allergic reaction, or death.

With any foreign material which is implanted such as a radiologic marker (EchoMark LP), there is risk of allergic reaction, infection, inflammation, migration (movement out of position), or extrusion (marker being forced out of the body). Biocompatibility testing (a test to evaluate how compatible is a medical device with your body's makeup) was completed by the Sponsor, and the data collected and the extensive prior use of the material in medicine, suggest the probability of such risk is low.

[redacted]

There is also a possibility that the fistula may slide out of the EchoMark LP, which may prevent the EchoSure device from measuring the flow, diameter and depth accurately. Standard of care methods for assessing the fistula would be available if this were to occur.

There is risk that the ultrasound scan may create mild discomfort on the wound site, similar to standard of care ultrasound. Standard of care methods for assessing the fistula would still be available if this were to occur.

If you have signs of allergic reaction, infection, inflammation, or extrusion (coming out from the body), the EchoMark may be removed and you will be monitored by your physician's standard of care, including physical exam and possibly ultrasound.

There is a small chance that confidentiality of your personal information may be lost. We are careful to minimize this risk. We will not put your name, medical record number, or any identifying information in the database that could link this information back to you. A study ID will be assigned to your medical record information stored in the data. Information linking the study ID number to your name and other personal identifiers will be stored in a separate secure location only accessible to study personnel.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will being in this research benefit me?

There are no known benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, you will receive close monitoring of you healing fistula and your participation may help us to treat patients better in the future. If so, this could improve your care in the future.

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

Instead of being in this research, you may choose to not participate in this study and have the standard AV fistula creation surgery and normal post-operative monitoring of the fistula healing per your surgeon's practice. Duplex ultrasound is an available alternative to assess and monitor your fistula's healing, and measure the blood flow, diameter, and depth of your fistula without the need for an implant.

DETAILED RESEARCH CONSENT

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.

[redacted]

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

If you take part in this research, you will be responsible for coming to your scheduled follow-up appointments for ultrasound examinations. Otherwise, your responsibilities will be identical to the standard AV fistula creation surgery. Those responsibilities will be discussed with you by your surgeon and are particular to his or her standard practice.

Could being in this research hurt me?

The study involves the creation of an AV fistula, therefore the risks of participating in this research include the risks associated with AV fistula creation which may include bruising, numbness, tingling and/or coolness in the extremity, thrombosis (blood clot), stenosis (narrowing of blood vessel), failure to mature, additional interventions, venous hypertension (elevated blood pressure inside your veins), swelling, irritation or pain, bleeding/hemorrhage, hematoma (bruising), seroma, wound problem, fever, steal syndrome, ischemia, embolism, infection, increased risk of congestive heart failure, nerve damage, vessel damage, pseudoaneurysm, compartment syndrome, heart problems such as arrhythmias, burns, problems due to sedation or anesthesia, sepsis, allergic reaction, or death

With the implantation of any foreign material such as a radiologic marker (EchoMark LP), there is risk of allergic reaction, infection, inflammation, migration (movement of marker), or extrusion (marker being pushed out of the body). Biocompatibility testing (a test to evaluate how compatible is a medical device with your body's makeup) was completed by the Sponsor, and the data collected and the extensive prior use of the material in medicine, suggest the probability of an allergic reaction is low.

[redacted]

There is also a possibility that the fistula may slide out of the EchoMark LP, which may prevent the EchoSure device from measuring the flow, diameter and depth accurately. Standard of care methods for assessing the fistula will still be available if this were to occur.

There is risk that the ultrasound scan may create mild discomfort on the wound site, similar to standard of care ultrasound. Standard of care methods for assessing the fistula would still be available if this were to occur.

If you have signs of allergic reaction, infection, inflammation, or extrusion, the EchoMark may be removed and you would be monitored by your physician's standard of care, including physical exam and possibly ultrasound.

[redacted]

There is a small chance that confidentiality of your personal information may be lost. We are careful to minimize this risk. We will not put your name, medical record number, or any identifying information in the database that could link this information back to you. A study ID will be assigned to your medical record information stored in the data. Information linking the study ID number to your name and other personal identifiers will be stored in a separate secure location only accessible to study personnel.

There could be risks to you that are currently unknown. Your doctor will tell you about any important new information learned during the study that might affect whether you want to continue to be in the study.

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

Taking part in this research will not lead to added costs for you. You or your insurance company will be billed for your routine care, which includes the surgery to create the fistula. Please talk to your study doctor to determine which costs will be billed to you or your insurance and which costs will be paid by the sponsor. The sponsor of the research study, Sonavex Inc., is paying the research site to conduct this study.

Will being in this research benefit me?

There are no known benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, you will receive close monitoring of you healing fistula and your participation may help us to treat patients better in the future. If so, this could improve your care in the future.

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

Instead of being in this research, you may choose to have the standard AV fistula creation surgery and normal post-operative monitoring of the fistula healing per your surgeon's practice. Duplex ultrasound is an available alternative to assess and monitor your fistula's healing, and measure the blood flow, diameter, and depth of your fistula without the need for an implant. Participation in any research study is voluntary.

What happens to the information collected for this research?

This section explains how your medical information will be collected. It explains how this information will be used and shared with other persons involved in the study. Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that could identify you personally such as:

- Name, address, and social security number
- Medical and mental health records
- Laboratory test results

[redacted]

You are being asked to allow the collection of your PHI. You are also being asked to allow the use and sharing of this information and information about you collected in the study and outside the study (e.g., outside hospital records, dialysis/cannulation records) with those individuals involved in this specific study and by law they must protect it. This includes investigators listed on this consent form and other personnel of the study site, the IRB, and your health insurance company. Medical information produced by this study will become part of your hospital medical record. If you do not give your permission by signing this form, you cannot be in this study. Study-related information will be stored in a locked location and will only be available to those members involved in the study.

Any PHI obtained in connection with this research study that can identify you will remain confidential and will only be used for the purpose of this study. In addition to the required study assessments, hospital billing data related to the treatment and management of your AV fistula may also be collected, if available. It will only be disclosed with your permission, except as required by law. However, once some of the organizations listed below receive your PHI, they may not be required to protect it and it may be released to others.

By signing this consent form you are allowing the release of, or access to, your PHI. You are also allowing the study doctor to share your medical information with:

- Sonavex, Inc. (sponsor). This includes all those that work on behalf of the sponsor to run the study including:
    - Its representatives
    - Its contractors (Clinical Research Organization and Research Monitors)
- Other doctors and health care professionals who are involved in the study
- The U.S. Food and Drug Administration (FDA)
- With any person or agency required by law

If you develop an illness or injury during your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study.

Your PHI will be collected, used, and shared with those noted above to make sure the research was done right and to evaluate the results of the research study.

PHI collected as a part of this research study may be used indefinitely.

[redacted] Your permission to use and disclose your PHI does not expire.

You may quit the study and revoke permission to use and share PHI at any time by contacting a member of the research staff in writing, at: [redacted]

If you withdraw your Authorization, you cannot continue to take part in the study. However, this will involve no penalty or loss of benefits to which you are otherwise entitled.

Further collection of PHI will be stopped if you choose to quit the study. However, PHI already collected may still be used.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission.

You have the right to see your medical information related to the study for as long as the study doctor keeps this information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

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, Sonavex
- People who work with the research sponsor
-
- Government agencies, such as the FDA
- The IRB that reviewed this research

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.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

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 855-818-2289, researchquestions@wcgirb.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
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

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?

Participation in any research study is voluntary. If you do not wish to take part, then you do not need to. If you decide to take part and later change your mind, then you are free to withdraw from the study at any time. Your decision will not affect your future medical care at this facility or your relationship with your doctor or other members of the medical team and there will be no penalty or loss of any benefits to which you may be otherwise entitled.

If you decide to leave the research early, the research team will promptly remove you from the study. This will consist mainly of cancelling your remaining appointments for ultrasound examinations of your fistula. There are no expected risks to this decision. This will not impact you receiving appropriate care for your AV fistula per your surgeon's standard practice.

Will I be paid for taking part in this research?

You will be paid for taking part in this research. For each follow-up visit you will be paid per visit as cash or cash equivalent (such as a gift card) and for the 6-month follow-up visit.

You will be compensated for the study visits you complete per the following payment scale:

Visit:	15 Day	30 Day	60 Day	90 Day	120 Day	150 Day	180 Day	365 Day	Total
Amount:									

Statement of Consent:

I have received written information concerning the research study "Prospective Feasibility Study Evaluating EchoMark LP Placement and EchoSure Measurements for Subjects Requiring Arteriovenous Fistulae" and I have 1had enough time to read through it.

In addition, I was provided with comprehensive verbal explanations about the EchoMark LP and EchoSure, including the purpose, procedures, possible benefits, risks, and obligations of the study. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I may decide to decline or stop participation at any time without affecting the quality of my health care.

I understand that I will be given a signed copy of the Subject Informed Consent Form to keep for my records and that I will be promptly informed of any new findings regarding this study.

I understand that the investigator has agreed not to reveal my identity and personal details of information about this study when it is published or presented in any public form. I also understand sections of any of my medical notes may be looked at by Sonavex, Inc or authorized designee or regulatory authorities, such as the FDA or the IRB where it is relevant to my taking part in this research study. I give permission to these individuals to access my medical records.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

Signatures:

I, (Print Full Subject Name) _____
hereby consent to take part in this study.

Signature _____ Date _____ Time: _____

Name of Person Obtaining Consent (printed) _____

Signature _____ Date _____ Time: _____

Note: All parties signing the Subject Informed Consent Form must date their own signature.

Patient's Consent for Disclosure of Medical Information

Date: _____

I, _____ (Patient Name) Date of Birth:_____

do herby consent that you release to:

- ❑ Nephrologist: _____
- ❑ Surgeon: _____
- ❑ Radiologist: _____
- ❑ Dialysis Facility: _____

(Print the Name of Title of the person(s) or organization(s) to which disclosure is to be made)

Confidential medical records including complete records, laboratory reports, procedure, treatment and dialysis records in the custody of:

- ❑ Nephrologist: _____
- ❑ Surgeon: _____
- ❑ Radiologist: _____
- ❑ Dialysis Facility: _____

(Print the Name of Title of the person(s) or organization(s) to which disclosure is to be made)

General Nature of Information to be Released and Dates:

Any and all information pertaining to dialysis treatment, treatment reports, discharge and follow-up information, laboratory results,

Additional:_____

_____

This consent shall be in effect for one (1) year from the date recorded on this consent. I understand that this consent is subject to revocation at any time, upon written notification by me, except to the extent that action has been take in reliance thereon. A photocopy or facsimile of this consent is as valid as the original.

Signature of Patient	Date
Signature of Witness	Date