CONSENT TO PARTICIPATE IN A RESEARCH STUDY
STUDY GROUP

Assessment of the ability to predict fascial closure using shear-wave elastography in patients with midline incisional hernias.

Study to be Conducted at: Prisma Health
Minimal Access Surgery
905 Verdae Boulevard, Suite 202
Greenville, SC 29607

Prisma Health
Greenville Memorial Hospital
701 Grove Road
Greenville, SC 29605

Prisma Health
Greer Memorial Hospital
830 S Buncombe Road
Greer, SC. 29650

Prisma Health
Hillcrest Memorial Hospital
729 SE Main Street
Simpsonville, SC 29681

Sponsor Name: Prisma Health, American Hernia Society Grant

Principal Investigator: M. Wes Love, MD (864-522-2100)

KEY INFORMATION
You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study doctor to explain anything you do not understand.

This study is being done to see if using shear wave elastography (SWE), an ultrasound imaging method used to measure the stretchiness of the belly wall muscles, improves surgical outcomes for participants with ventral incisional hernias (hernia in the middle of the belly) who are having open retromuscular ventral hernia repair (VHR) surgery. There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. It is not possible to know whether you may benefit from participating in this study. The information gained from this study may be useful and may help others with ventral incisional hernias. The alternative to participating in this study is simply not to participate.

The Institutional Review Board of Prisma Health has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

PURPOSE

You are being asked to participate in this study because you have a ventral incisional hernia and plan to undergo open retromuscular VHR. Your open retromuscular VHR surgery will involve an incision (cut) in your belly. Then, your doctor will place a mesh over your hernia and close your incision with sutures (stitches).

The purpose of this study is to see if SWE can be used as a tool to measure the elasticity (stretchiness) of the belly wall muscles and improve surgical outcomes for participants who are having open retromuscular VHR.

About 70 participants will be enrolled in this study at Prisma Health.

Your participation will last for the duration of your surgery.

HOW THE STUDY WORKS

If you agree to participate in this study, the following procedures will be done:

- Information will be collected about you, including demographic (such as age, sex, race) and medical history information as well as information regarding your hernia and the outcomes of your surgery.
- Ultrasound images will be taken of your belly (area where your hernia is located). The ultrasounds will be taken in three different ways: with minimum pressure, with maximum pressure, and while you are doing a breathing technique called Valsalva.
- You will have your open retromuscular VHR surgery.
- An analog spring-tensiometer (an instrument that measures tension) will be used to assess the tension needed to close your wound.
- Your doctor will place a mesh over your hernia and close your incision with sutures (stitches).

The ultrasound images and the tensiometer measurements will be done for study purposes and these procedures are not part of your standard care.

POSSIBLE RISKS

There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

This study includes a surgery that is associated with certain risks. These risks are described in the separate treatment consent form.

POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. The information gained from this study may be useful and may help others.

ALTERNATIVE (OTHER) TREATMENTS
The decision to participate in this study is entirely up to you. The alternative to participating in this study is simply not to participate. If you decide not to participate in the study, you will not be penalized in any way.

NEW INFORMATION
Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you.

COST TO YOU FOR PARTICIPATING IN THIS STUDY
Study funds will pay for all study-related items and services required by the research. We will bill you or your health insurer for items and services that are not part of the research and are part of your routine care. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about costs from taking part in the research, please speak with the study doctor or staff.

PAYMENT FOR PARTICIPATION
To You:
You will be paid $25 after you undergo ultrasound imaging of your belly.

To process your study payment, you will be asked to complete a W-9 form with your name, address, date of birth, and Social Security number. If you receive $600 or more for study participation in this research study, or a combination of studies at Prisma Health in one tax year, Prisma Health will send you an IRS Form 1099 for tax purposes.

You will be paid via ClinCard, a reloadable debit card. The ClinCard program is owned by a company called Greenphire. The study team will give Greenphire your name, address, date of birth and Social Security number as part of the payment system. Greenphire will only use this information to make sure you get paid. Greenphire will not use your information for any other purposes, and they will not give or sell your information to any other company. The study team will provide you more information about the ClinCard program following study enrollment.

To Institution:
The Prisma Health is being funded by the sponsor for staff and administrative costs associated with conducting this study.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION

We will provide you the care needed to treat any injury, or illness, that directly results from taking part in this research study. We reserve the right to bill your insurance company, the sponsor or other third parties for the care you get for the injury. You may be billed for these costs. For example, if the care is billed to your insurer, you will be responsible for the payment of any deductibles and co-payments required by your insurer.

The study sponsor, Prisma Health, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

However, if you decide to stop study participation, you are encouraged to talk with your doctor regarding safe removal from the study. Further treatment would be discussed at that time.

If your participation in this research study is stopped, your study doctor will discuss any tests or procedures that might be needed for your health and safety, but you may refuse any or all of these tests or procedures. Following this discussion with your study doctor, you still have the right to refuse any or all of these tests or procedures.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Some of the organizations/entities that may receive your information are:

- The study sponsor and any company supporting the study (the sponsor's authorized representatives)
- The Institutional Review Board, which is a group of people who review research with the goal of protecting the people who take part in the study

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written

notice to the study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

If you have any questions about the privacy of your health information, please ask the study doctor.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Prisma Health Office of Human Research Protection for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

Principal Investigator Name: M. Wes Love, MD Telephone Number: (864-522-2100)

CONSENT TO PARTICIPATE

The study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given the opportunity to review my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

_____
Printed Name of Person Obtaining Consent

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

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