RESEARCH SUBJECT CONSENT FORM

Title: SUNN STUDY Screening for Undiagnosed NAFLD and NASH

Protocol No.: flf-screen 1
WIRB® Protocol #20182311

Sponsor: Fatty Liver Foundation

Investigator: Wayne Eskridge, BS
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Daytime Phone Number: 208-860-0546

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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.

You have the opportunity to take part in a study that tests the stiffness of your liver and simultaneously measures the amount of fat in the liver. You do not have to take part in this study if you do not want to. Your participation is voluntary. The purpose of this information and consent form is to tell you about the study and your role in it. Our healthcare staff will answer any questions you have about the study or the information you read in this form. You should read this form carefully and ask the staff to explain any words or information that you do not understand. Your questions should be answered clearly and to your satisfaction.

In order to do the study, we will need to collect limited medical information, but it will not identify you personally. We will then perform an ultrasound examination of your liver using a machine called the FibroScan®. While the FibroScan is being done, you will need to lie down on your back during the examination, and then a certified FibroScan operator will take a minimum of 10 quick and painless valid measurements with the ultrasound probe on the right upper side of your abdomen. The examination usually takes 5 to 10 minutes. By signing this consent form, you are permitting us to collect your demographic information and to perform the FibroScan examination. You should not sign this form if you have any questions that have not been answered.

The investigator is the sponsor, and is paying for this study.

PURPOSE OF THE STUDY

This is a “population study” of patients that have chronic health concerns, but no diagnosis of liver disease, to determine how many of them have livers that are stiffer than normal.

"Population study" means that the purpose of the study is to gather statistical information about people who are not known to have liver disease in order to find out how many have

indications of a risk for silent liver disease. Livers can be damaged without any symptoms and become stiff. This study seeks to find out how common that condition is in people with other chronic health conditions. Livers may also become filled with fat which can become a health risk and the FibroScan measures fat content also.

The FibroScan is a non-invasive test (similar to an ultrasound), meaning it has no effect on the body and is painless. As part of this study you will not receive any medication or treatments of any kind. You will be given information about the health concerns that are being studied and given educational materials which may help you practice a healthy lifestyle.

To participate in the study you cannot have a diagnosed liver disease.

If you qualify for the study, you will receive

- Educational materials about diet and other lifestyle issues which may be unhealthy
- A FibroScan test of your liver
- Printed output from the FibroScan test. Interpretation of the test results require a professional.
- Information about resources available to you medically and/or nutritionally to help you understand the results of your test and what steps you might take following the test
- The study is a single test and there will be no follow up by us. You will be offered community services and professional contacts that will be provided to you after the test
- You will receive information about how you may contact a hepatologist, a liver specialist, about the test results but consulting with the specialist is your responsibility. The study sponsor does not provide diagnosis or medical care of any kind.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study is expected to last up to twelve weeks or until one thousand adults have been tested. There minimum number of participants is 400 but there will be a maximum of one thousand patients tested.

Your participation will be a single FibroScan on one day.

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 measure liver stiffness in a group of patients who are coping with chronic health conditions but are not known to have a liver disease. This will help measure how many people may be at risk to develop liver disease in the future.

How long will I be in this research?
We expect that your taking part in this research will be for one test on one day.

What happens if I agree to take part in this research?
Before receiving the FibroScan, you will be asked to read and sign this consent form and provide some general information about yourself and medical conditions you believe you have. You will not be asked to provide any information that personally identifies you. The study questions are of a general nature to be used in statistical analysis. You will be asked to identify any medical conditions that you believe you have but no information will identify who you are.

The investigator will ask some questions to find out if you can be in the study.

- You must be at least 18 years old
- You cannot be included if you already know that you have a liver disease
- Pregnant women cannot be screened
- Patients with battery operated, implanted devices of any kind cannot be screened
- Being very overweight may make the test unreliable

Study Procedures:

You will be asked to lie down on your back during the examination, and then a certified FibroScan operator will apply a water-based gel to your abdomen. They will then take a minimum of 10 quick and painless measurements with the ultrasound probe on the right upper side of your abdomen. The examination takes 5 to 10 minutes.

After the FibroScan test, you will receive a copy of the test and receive additional information about diet and lifestyle. You will be provided with information about how you may contact follow up medical resources. You will be asked about how you feel about the testing and its value to you. You will be given the opportunity to receive additional information about health and clinical trials through online educational programming. Participation in the education is voluntary and not part of the study.

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

- If you take part in this research, you will volunteer to have a single noninvasive liver stiffness test
- You will fast for at least 3 hours prior to having the test
- After the test you will be asked to provide information about what you think the value of the testing is for you personally.
- You will have no other responsibilities as part of the study but you will be offered information about how to take next steps that may be beneficial to you.

Could being in this research hurt me?

- While the FibroScan ultrasound probe touches the right upper side of your abdomen, you may feel a gentle tapping sensation on your skin during the examination, like the flick of a finger tapping on your skin.
- Fasting may cause lightheadedness. If you are diabetic or have other medical conditions, with side effects from fasting, do not participate without first talking with your doctor if a fast of 3 hours may affect you.
- Pregnant women or people with battery-operated, implanted cardiac devices (cardiac or otherwise, e.g., pacemakers or implantable cardioverter defibrillators [ICDs]) cannot have a FibroScan.
- Also, in patients with fluid in their abdomen (ascites), the examination may fail and would not be useful.
- A very high BMI makes the test unreliable and participating will not be of value.

ADDITIONAL RISKS OR DISCOMFORTS

During the test you will be asked to lie on your back on a table with your right arm over your head. Some patients may have difficulty being on the table or positioning themselves for the test. Accommodations will be made if possible but some may not be able to move in that manner and should not take the test.

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

You must tell the investigator or study staff about any side effects that you have. If you are not honest about any side effects, you may harm yourself.

There are no known side effects (or rare side effects) of the FibroScan.

There is the risk of a loss of confidentiality of your research-related information.

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

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

Participating in this study is free to you.

Taking part in this research may lead to added costs to you such as the cost of medical care or testing that you choose after receiving the results of the test. The cost of any consultation or medical care following the test is the responsibility of you or your insurance company.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. The goal of the study is to better understand the health of the community so your participation may benefit you as a member of the community in the future.

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 is not being collected as part of this study so it will not become a part of your medical record or be personally identifiable. The community data will be available to any of these groups

- 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
- Other groups working to improve the health of the community

We may publish the results of this research but no personal information will be part of the data.

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 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 (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?
This study is non-invasive with no known risks so any post-test medical procedures are the responsibility of the patient. Please be aware that some insurance plans may not pay for claims of research-related injuries. You should contact your insurance company for more information.

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. Since the study is noninvasive and involves a single test, a typical reason that you might be removed would be failure to keep the appointment.

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

What happens if I agree to be in this research, but I change my mind later?
You may change your mind at any time with no cost or consequences to you.

Will I be paid for taking part in this research?
You will not be paid for taking part in this research.

Your data may be used for commercial profit. You will not share in this commercial profit.

Statement of Consent:

By signing this form you give your consent to taking part in this research.

Signature of adult subject capable of consent	Date

Signature of Investigator or Designee Obtaining Consent	Date

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

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RESEARCH SUBJECT CONSENT FORM

Title:	SUNN STUDY Screening for Undiagnosed NAFLD and NASH
Protocol No.:	flf-screen 1 WIRB® Protocol #20182311
Sponsor:	Fatty Liver Foundation
Investigator:	Wayne Eskridge, BS 3938 E Shady Glen Ct Boise, Idaho, 83706-6923 USA