CONSENT FORM FOR RESEARCH PARTICIPATION
BronxCare Health System

Study Title: Assessment of liver steatosis and fibrosis using elastography in patients with Type-2 Diabetes Mellitus with normal liver function tests.

Principal Investigator: Makker Jasbir, MD

Fellow Researcher: Hassan Tariq MD, Madhavi Ravi, MD and **Kishore Kumar Dewnani ,MD**

IRB Study Number:

We, Jasbir Makker, MD , Hassan Tariq , MD and Madhavi Ravi , MD and Kishore Kumar Dewnani , MD are physicians in the division of Gastroenterology, department of Medicine at Bronx care health system. We are conducting a research study which I invite you to take part in. This form has important information about the reason for doing this study, what we will ask you to do if you decide to be in this study, and the way we would like to use information about you if you choose to be in the study.

Why are you doing this study?
You are being asked to participate in a research study because you are a diabetic patient. The purpose of the study is to identify fat content in the liver (steatosis) of diabetic patients, which is an indirect measure of the degree of stiffness secondary to fat in your liver.if these are present they are considered to be findings that increases your risk for progression to advanced fibrosis and cirrhosis, and hence you will need close monitoring.

What will I do if I choose to be in this study?
Participants should agree to come in for a single visit in order to get a non-invasive scan of the liver called a fibroscan. A fibroscan (also called sheer wave elastography) can detect steatosis and liver stiffness in your liver if they are present. It is a simple test in which a probe will be placed between your ribs on the lower right side of your chest where your liver is located while you are lying down. It is similar to an ultrasound exam and a sound signal will be sent from the probe so that the measurements can be done. It causes no harm to you and is also painless.
At the visit your weight, waist circumference and BMI will be measured. If required, we will refer to nutritionist and will emphasise on weight loss, healthy eating habits and regular exercise. you will also undergo a blood test to check your liver function if you have not had one done already in the last 6 months.

Study time: Study participation will take approximately 20 minutes of total time.

Study location: All study procedures will take place at Health Wellness Clinic located at Mt Eden Parkway, Bronx, NY 10457.

What are the possible risks or discomforts?

There is no risk of any kind of bodily harm with fibro scan as it is non-invasive and only uses a sound signal, similar to an ultrasound examination.
As with all research, there is a chance that confidentiality of the information we collect from you could be breached – we will take steps to minimize this risk, once the information is collected .patient identifiers will be deleted and the data will be de-identified. Records will be reviewed by site study personnel only.

What are the possible benefits for me or others?

There may be no direct benefit to you,but if you are found to have liver stiffness, the results will be communicated to your doctor so that they can follow you more closely for future complications. If your liver function test is done when you are being screened for entry into this study and is abnormal, further testing will be done to evaluate for the cause of the abnormal liver function that may include another ultrasound and blood tests. This further testing will be done as standard of care and not part of this research study. Also, study results may be used to conduct further studies to change and improve current practice of medicine and hence may help people with diabetes mellitus in future.

How will you protect the information you collect about me, and how will that information be shared?

Results of this study may be used in publications and presentations. your study data will be handled as confidentially as possible. if results of this study are published or presented, individual names and other personally identifiable information will not be used.

To minimize the risks to confidentiality, all documented names and medical record numbers collected during the chart review, will be assembled to database and all patient identifiers and sensitive information will be erased. Records will be reviewed by site study personnel only.

Sharing of data collected for use in future research studies or with other researchers :

We might share the data that we collect about you with other researchers. we will remove any information that could identify you before we share it. If we think that you intend to harm yourself or others, we will notify the appropriate people authorities of this information.

Financial Information

Participation in this study will involve no cost to you. You will not be paid for participating in this study. Food Vouchers and metro card will be provided during each visit.

Disclosure of alternatives

In addition to fibroscan , liver fibrosis can be assessed by liver biopsy where a needle is inserted into the liver and a small biopsy specimen is taken for review . Other alternative but not as good as liver biopsy ARE blood tests like Fibrasure which can indirectly help in assessing liver fibrosis. At this time based on current evidence-based medicine, there is no recommendation for screening patient with diabetes for liver fibrosis. If you choose not to be a part of study, fibroscan will not be performed.

What are my rights as a research participant?

Participation in this study is voluntary. You do not have to answer any question you do not want to answer. If at any time and for any reason, you would prefer not to participate in this study, please feel free not to. If at any time you would like to stop participating, please let us know. We can take a break, stop and continue at a later date, or stop altogether. You may withdraw from this study at any time, and you will not be penalized in any way for deciding to stop participation.
If you decide to withdraw from this study, the researchers will ask you if the information already collected from you can be used.

What if I am a employee of BronxCare Health System ?

You may choose not to participate or to stop participating in this research at any time. This will not affect your employment, or any other aspects of your relationship with Bronx Care Health System.

Who can I contact if I have questions or concerns about this research study?

If you have questions, you are free to ask them now. If you have questions later, you may contact the researchers at BronxCare Health System, Madhavi Ravi, Ph # 917-634-1510, Hassan Tariq Ph # 347-993-0791 or Kishore Kumar Dewnani Ph # 917-355-4731.

If you have any questions about your rights as a participant in this research, you can contact the following office at BronxCare Health System.

Institutional Review Board
BronxCare Health System,
1650 Selwyn Avenue, 12 H
Bronx, NY-10457.
Ph # 718-960-1239

Privacy/Confidentiality

The investigator, Jasbir Makker MD, Hassan Tariq MD , Madhavi Ravi MD and Kishore Kumar Dewnani MD will use and may share personal health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam, and

laboratory test results. Some of these tests may have been done as part of your regular care. The investigator will use this information about you to complete this research.

By signing this authorization, you allow the investigator to use your personal health information to carry out and evaluate this study. You also allow the investigator to share your personal health information with the following:

- The BronxCare Health System Institutional Review Board
- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies as required by law

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the investigator has this information. However, by signing this authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this authorization at any time, but you must notify the investigator in writing. Send your written withdrawal notice to:

Principal Investigator's Name:	Jasbir Makker MD
Address:	1650 Selwyn Avenue , Suite 10C, Bronx , NY, 10457
	Or
IRB Chairperson:	Dr. Jonathan Bella
Address:	BronxCare Health System 1650 Selwyn Avenue 12 H Bronx, NY 10457

If you withdraw from the study and withdraw your authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed.

If you withdraw from the study but do not withdraw your authorization, new personal health information may be collected until this study ends.

Expiration and Revocation :

□ Upon the conclusion of the research study.

The investigator will keep this authorization for at least 6 years.

Statement of Agreement

I understand that my participation is voluntary and that my refusal or withdrawal will involve no loss of benefits. I understand that if I do not sign this authorization form I cannot participate in this research study or receive study-related treatment. If I withdraw this authorization in the future, I will no longer be able to participate in this study.

If you are injured as a result of being in this study you will either receive immediate necessary treatment or you will be told where you can receive treatment. You or your insurance company will be responsible for these charges. All records identifying the subjects will be maintained confidential except as outlined above.

Further information concerning this research may be obtained from Dr. Makker, the investigator, who can be reached at 718-518-5014 or from the Chairman of the Institutional Review Board, Dr. Jonathan Bella (718) 960-1239, Monday through Friday, 9:00 a.m. to 5:00 p.m. who should be contacted in all instances of research-related injury or inquiries concerning the rights of research subjects.

Participant's Name: [redacted] (Print)

Participant's Signature [redacted] Date: [redacted]

Person Obtaining Consent: [redacted]
(Print)

Person Obtaining Consent Signature: [redacted] Date: [redacted]

Witness Name: [redacted]
(Print)

Witness Signature: [redacted] Date: [redacted]