Northwell Health
Consent for Participation in a Research Study

Campus: Cohen Children's Medical Center (CCMC)
269-01 76th Ave, New Hyde Park, NY 11040
Title: Role of probiotics in treatment of pediatric nonalcoholic fatty liver disease (NAFLD) patients by assessing with fibroscan.
Principal Investigator: Shari Sheflin-Findling, DO
Facilities: Pediatric Gastroenterology, Liver Disease and Nutrition at Cohen Children's Medical Center (CCMC).

About this research
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

Taking part in this research study is voluntary
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with department of pediatric gastroenterology.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The goal of this study is to evaluate the role of probiotics in the treatment of pediatric nonalcoholic fatty liver disease (NAFLD).
What will happen to me during the study?	1): Participants will receive either probiotics Lactobacillus rhamnosus strain GG (10 billion CFU) oral capsule daily or a substance with no therapeutic effect (Placebo) oral capsule daily.

	2): Liver imaging (Fibroscan) will be performed during each visit to assess amount of fat in liver and stiffness of liver. 3): Results of blood tests performed as part of standard of care will be collected. 4): Weight and BMI will be checked during each visit 5): Stool samples will be collected (Baseline, 3 months and 6 months)
How long will I participate?	Your participation in this research study will last 6 months and will consist of a total of 3 office visits.
Will taking part expose me to risks?	This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. There are no major health risks in study participation as participants need taking probiotic daily, providing stool samples and undergoing fibroscan at requested times. There is no known risk to the ultrasound (elastography) measurements. Participants may experience mild bloating, gas or digestive gurgling as a result of taking the probiotic or placebo. Probiotics rarely cause allergic reactions. There is minimal risk of loss of confidentiality.
Are there any benefits to participation?	There are no known immediate benefits to participation in this study. Implementation of the more direct measure of liver fat via special sonogram known as Fibroscan may further highlight the shortcomings of formal sonogram and liver enzyme (ALT), therefore altering current pediatric guidelines. Furthermore, knowledge from this study may lead to the exploration of other variables such as the role of probiotics in NAFLD treatment.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

This consent form is written from the point of view of a research participant. If the parent or legal guardian of a minor or a legally authorized representative will be providing consent, the words "you" and "your" should be read as ("your child" or "the research participant").

Introduction

You child is being asked to join a research study. The purpose of a research study is to answer specific questions.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?

Nonalcoholic fatty liver disease (NAFLD) is a chronic liver disease resulting from excessive fat accumulation in the liver. The goal of this study is to evaluate the effect of probiotics in treatment of nonalcoholic fatty liver disease (NAFLD) by assessing with fibroscan in pediatric patients with NAFLD. Fibroscan is an ultrasound technology that developed in recent years which is commonly used in many healthcare systems. Fibroscan is a non-invasive ultrasound-based method that uses to assess liver tissue stiffness and to assess fat in liver. This is an

important study as current pediatric guidelines only recommend lifestyle modifications for the treatment of NAFLD and using ALT (liver enzymes) and sonogram to assess improvement. You are being asked to participate in this study because you were diagnosed with NAFLD through screening blood work (elevated ALT) and regular sonogram.

How many people will take part in this study?
This research study hopes to enroll 48 patients in each Group, for a total of 96 participants.

Expected duration of subject's participation
If you choose to take part in this study, the study procedures will last for 6 months, and you will be followed for another 6 months. You will be asked to attend 3 visits that will last 30 minutes each overa period of 6 months.

What will happen in this research study?
Once you have been informed about the study, have read and reviewed consent form with all of your questions answered and signed consent/assent, you will be enrolled in this study. You will get following suggestions:

- Life style modification will be suggested to you as per North American society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) NAFLD guidelines. Life style modification sheet will be provided to you.
- We will do fibroscan once every 3 months over a period of 6 months
- Blood will be drawn as part of standard of care every 3 months and the study team will be using the results of those blood tests for the purposes of this study
- We will give you probiotics Lactobacillus rhamnosus strain GG (10 billion CFU/day) or a substance with no therapeutic effect (Placebo)
- Participants will not know whether they are receiving the probiotics or a placebo
- We will collect a stool sample at the time of diagnosis, at 3 months and at 6 months.

Possible Benefits of the research study
This research may or may not benefit you directly. However, knowledge gained from fibroscan and use of probiotics may help change future care of pediatric patient with NAFLD.

Possible risks and discomfort of the research study
This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. There are no major health risks in study participation as participants need taking probiotic daily, providing stool samples and undergoing fibroscan at requested times.

- There is no known risk to the fibroscan, it's a special sonogram which measures fat and firmness of liver.
- You may experience mild bloating, gas or digestive gurgling as a result of taking the probiotic or placebo. Probiotics rarely cause allergic reactions.

- There is minimal risk of loss of confidentiality. However, all of your data will be assigned a code number and your name will not appear with the data. We will keep a record or your name and code number locked in the department of Pediatric Gastroenterology. Only staff on the study will have access to this link.

Incidental Findings
Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

Will I receive my results?
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Liver enzyme result (ALT) will be provided and you will be notified via phone.

Are there any costs for being in this research study?
This research study is funded by department of Pediatric Gastroenterology, Liver disease and Nutrition. Probiotics and placebo are donated by Amerifit, Inc/I-Health Inc which produces Lactobacillus rhamnosus strain GG. Blood test is standard of care and study team will be using the results of those blood tests for the purposes of this study as well. You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?
You will not be paid to participate in this study.

Will my biospecimens be used to create a marketable product? And if so, will I receive payment?

Your specimens will not be used to create a marketable product.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- Failure to follow instructions,
- Failure to show up for study visits, or
- The study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

HIPAA Section

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of blood tests, fibroscan images and stool analysis. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversees research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send letter to the researcher at the following address:

Dr. Kanya Ahuja
Division of Pediatric Gastroenterology, Liver Disease and Nutrition
1991 Marcus Ave
Suite M100
Lake success, NY 11042
Phone # 516-472-3650

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected like fibroscan report, ALT and stool analysis.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Will my information be used for research in the future?

Information or specimens collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future

research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent

Does the investigator of this study receive money if you take part?

The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr Kanya Ahuja at (516) 472-3650. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Participant's printed name

_____
Printed Name of Parent/Legal guardian

_____ _____
Signature of Parent/Legal guardian Date

Description of signer's authority to act on behalf of the participant: _____

_____ _____
Witness's Signature Date

Witness's Printed Name: _____

If Participant is 18 years of age

_____
Participant's printed name

_____ _____
Participant's Signature Date

Investigator's Statement
I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name