University of California, San Diego
Consent to Act as a Research Subject

National Institutes of Health (NIH)
Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN)

Farnesoid X Receptor Ligand Obeticholic Acid in NASH Treatment (FLINT) Trial
Magnetic Resonance Imaging Research
Informed Consent

Drs. Rohit Loomba, Heather Patton and Thuy Anh Le, are asking you to have a Magnetic Resonance Imaging (MRI) exam because you have nonalcoholic steatohepatitis (NASH) and you have agreed to participate in the FLINT Trial research study. If you do not agree to have an MRI exam, you may still participate in the FLINT Trial.

If any part of this consent statement is unclear, please ask the study doctor or other study staff to explain it to you so that you understand. You are entitled to have any questions about the MRI exam answered to your satisfaction. Before making your decision, we ask you to think about it at home and to discuss it with your family or friends. If you decide to have an MRI exam, we will ask you to give your consent by signing in the space provided below. The study staff will also sign the statement. We will give you a copy of the signed statement. We will also give you instructions for contacting the study staff if you need to contact them during the study or after the study has ended.

PURPOSE

If you agree to have an MRI exam, the machine will take images of the inside of your body. The MRI exam will use a special technique to determine the location and amount of fat in and around your liver. In the future, this procedure may provide doctors with alternatives to liver biopsy for the diagnosis of NASH and for monitoring the progression of NASH.

DIFFERENCE FROM OTHER PROCEDURES IN THE FLINT TRIAL

This consent is only for the MRI exam, which will be performed in addition to the other procedures you consented to in the FLINT Trial. Therefore you can refuse this part of the research program and still participate in the FLINT Trial.

PROCEDURES

If you decide to have an MRI exam, it will be performed during or around the time of your screening visit and the week 72 visit. If an MRI scan has been done within 90 days of the screening liver biopsy, results from the scan can be used for this study if the same protocol was performed. The data will be included in the study. Before your exam, you will be asked to fast for at least four
hours. You will lie on your back on a table and be asked to remain still while the scanner takes images of the inside of your body. These images will be sent to the NASH CRN Radiology Reading Center located at the University of California, San Diego. The data that will be obtained from your images will be analyzed and stored for further studies.

RISKS AND DISCOMFORTS

MRI: MRI scanning uses strong magnets to obtain images of the liver. It does not use radiation. The MRI scan will take 15-30 minutes and you will be lying on your back in the scanner tube. There is a weight limit that may prevent you from having an MRI exam. You will be asked to complete a safety screening sheet before you have your MRI scan to determine whether it is safe for you to have the test.

Common risks associated with MRI are as follow:

1. The magnetic resonance scanner is a long narrow tube that is open on both ends. A small number of individuals experience claustrophobia once inside. You will be able to signal the investigators with a squeeze ball device at an time to pause or stop the study or simply to ask questions.
2. The scanner produces loud banging noises while acquiring images. You will be given a set of earplugs to help with the noise.
3. There are no known effects from exposure to magnetic fields. However, some patients might become anxious during scanning. If this happens to you, you can stop the procedure at any time. You can also experience some discomfort and fatigue from lying in a confined space during the imaging.

If you have any metal clips, plates, or a pacemaker in your body, you should tell the investigator. MRI may not be appropriate under some of these conditions; a cardiac pacemaker; metal fragments in the eyes, skin or body, heart valve replacement, brain clips, venous filter, history of sheet metal work or welding, aneurysm surgery, intracranial bypass, renal or aortic vascular clips; prosthetic devices such as middle ear, eye, penile implants, or joint replacements; hearing aide, neurostimulator, insulin pump, IUD, pregnancy; vascular shunts or stents; metallic implants, plates, pins, wires or screws; permanent eyeliner or eyebrows.

General risks: Every effort will be made to maintain your privacy; however, it is possible that others may learn about the information acquired from your medical records.

BENEFITS

There are no direct benefits to you. Your MRI images may help researchers to better understand NASH and other health conditions. You will not be paid to take part in this MRI study.

Sometimes research results in findings or inventions that have value if they are made or sold. These findings or inventions may be patented or licensed, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits may be paid back to the researchers and the organizations doing this study, but you will not receive any financial benefits.

DATA REPOSITORY

At the end of the study, any data collected on your MRI exam will be sent to the NIDDK Data Repository that collects, stores, and distributes study data from people with many kinds of disorders and from healthy people. The purpose of the NIDDK Repository is to make data available for health research. Your data will be used by the researchers carrying out the FLINT Trial, but they also may be used by other researchers, both during the study and after it ends. Your data will be labeled with a code number before they are sent to the NIDDK Data Repository. Your name, address, social security number, medical record number, date of birth, and other personal identifiers will not be sent to the NIDDK Data Repository.

CONFIDENTIALITY

Your participation in this study will be kept confidential and your name, address, and other personal identifying information will not be made known to anyone other than study staff at this clinic. Your health and medical information will be sent to the Data Coordinating Center located at The Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. The information will be labeled with only an identifying number and code that cannot be linked to your name or other personal identifiers except at the clinical center where you complete visits. When results from this study are published in medical literature, you will not be identified by name.

Representatives of the National Institutes of Health, Data Coordinating Center, or other experts may review your records during visits to the clinic as part of the ongoing monitoring of the study. In addition, representatives from the United States Food and Drug Administration (FDA) or the Institutional Review Board at the clinic may review your records, including your medical records, as part of the ongoing monitoring of the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The Certificate protects us from being forced to disclose information that may identify you, even by a court subpoena. We are also protected from demands for your information made by federal, state, and local civil, criminal, administrative, legislative, or other sources. However, the Certificate cannot be used to resist a demand from the U.S. Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA. The Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in the research. Even with the Certificate of Confidentiality, if the study staff learns of possible risk of harm to yourself or others, we are required to notify the proper authorities.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this MRI study. If you decide to undergo a MRI exam, you may withdraw or modify your consent at any time during the FLINT Trial. If you decide to withdraw your consent entirely, your images will be destroyed. Your decision will not change your participation in the FLINT Trial nor will it change your future medical care at this institution.

COSTS
You will not be billed for any part of this study and there are no costs to you.

COMPENSATION
You will be compensated $50 for each MRI visit. If you do both MRIs, one at the screening visit and one at the week 72 visit, you will receive a total of $100.

CARE IF HARMED
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program office at (858) 455-5050 for more information about this, or to inquire about your rights as a research subject, or to report research-related problems.

QUESTIONS
Dr. Loomba and/or _____ has explained this study to you and answered your questions. If you have questions you may reach either of the study doctors, study staff or Thu Nguyen 619-543-5459.

After Hours:
UCSD Hospital Operator at 619-543-6737 – Ask the operator to page Drs. Loomba, Patton or Le. Let the operator know that you are a research participant.

CONSENT
I have read the above information about the purpose of the study as well as the potential benefits and risks of participation in the study. I have had an opportunity to discuss it with Dr. _____ or other involved study staff and to ask my questions about the study procedures. All of my questions have been answered to my satisfaction. All oral and written information and discussions about the study are in English [or in a language in which I am fluent]. My signature below indicates that I voluntarily consent to participate in this MRI research study.

_____ _____
Patient (printed name) Date

_____
Patient (signature)

I, the undersigned, have fully explained the relevant details of this study to the patient named above), and will provide him/her with a copy of this signed and dated informed consent form.

_____ _____
Person obtaining consent (printed name) Date

_____

Person obtaining consent (signature)

SUBJECT BILL OF RIGHTS

As a subject in a research study or as someone who is asked to give consent on behalf of another person for such participation, you have certain rights and responsibilities. It is important that you fully understand the nature and purpose of the research and that your consent be offered willingly and with complete understanding. To help you understand, you have the following specific rights:

1. To be informed of the nature and purpose of the research in which you are participating.

2. To be given an explanation of all procedures to be followed and of any drug or device to be used.

3. To be given a description of any risks or discomforts, which can be reasonably, expected to occur.

4. To be given an explanation of any benefits which may be expected to the subject as a result of this research.

5. To be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.

6. To be informed of any medical treatment which will be made available to the subject if complications should arise from this research.

7. To be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.

8. To be made aware that consent to participate in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of your medical care.

9. To be given a copy of the signed and dated written consent form.

10. To not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching your decision to consent or to not consent to participate in the research.

If you have any further questions or concerns about your rights as a research subject, please contact the research doctor or the UCSD Human Research Protections Program at 858-455-5050 during normal working hours.