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
DNA Banking for Current and Future Genetic Research

Informed Consent

Drs. Rohit Loomba, Heather Patton and Thuy Anh Le, are asking you to donate your blood for genetic research because you have nonalcoholic steatohepatitis (NASH) and you have consented to participate in the FLINT Trial research study. If you give us permission, your blood sample will be used as a source of DNA to study the genetic reasons for NASH. Also, some of your DNA sample will be saved for future genetic research related to NASH and also for future research that may not be related to NASH. If you do not agree to have your DNA sample used for genetic research, 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 genetic research 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 donate your blood for DNA banking, 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

Studies have been done indicating that genetic factors contribute to NASH. If you agree to take part in this genetic study, your genes will be studied to identify a relation between NASH and certain parts of DNA. In the future, this research may provide doctors with alternatives to liver biopsy for the diagnosis of NASH and for monitoring the progression of NASH. This genetic research may also help researchers to develop drugs for treatment of NASH.

DIFFERENCE FROM OTHER SAMPLES COLLECTED IN THE FLINT TRIAL

Please note that this blood sample, which will be used as a source of DNA, is additional to the blood samples which you consented to donate and have banked when you consented to participate in the FLINT Trial. Those are required for serum and plasma banking. This consent deals with consent for genetic or DNA analysis of an additional blood sample. Because DNA or genetic analysis can be used for research on many diseases, and because DNA can reveal much information about you, consent for DNA research is requested separately. This separation allows you to refuse this part of the research program and still participate in the FLINT Trial.

PROCEDURES

If you decide to donate your blood, we will draw 20 mL (approximately 1 ½ tablespoons) of blood from your forearm. Your blood sample will be sent to the NIDDK Genetics Repository where DNA will be obtained from your blood sample and stored for further studies.

RISKS AND DISCOMFORTS

Blood drawing: Blood drawing is mildly painful and can cause bruising and very rarely, fainting, blood clots or an infection at the site.

General risks: There is a potential risk to your privacy. While every effort will be made to maintain your privacy, it is possible that others may learn about the information acquired from your DNA and such a breach may lead to problems with your family members (for example, learning who is the true parent of a child) or problems getting insurance or a job.

BENEFITS

There are no direct benefits to you. Research conducted on your DNA may help researchers to better understand NASH and other health conditions afflicting humankind. You will not be paid to take part in this genetic study

DNA BANKING AND DATA REPOSITORY

Your blood sample will be sent to the NIDDK Genetics Repository to obtain a DNA sample from your blood cells for banking. At the end of the study, any data collected on your DNA sample will be sent to the NIDDK Data Repository.

The NIDDK Repositories are a research resource supported by the NIH that collect, store, and distribute DNA and study data from people with many kinds of disorders, from unaffected family members, and from healthy people. The purpose of NIDDK Repositories is to make samples and data available for use in health research. Your DNA sample and 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 DNA sample and data may be stored indefinitely.

Your blood sample and data will be labeled with a code number before they are sent to the NIDDK Genetics and Data Repositories. Your name, address, social security number, medical record number, date of birth and other personal identifiers will not be sent to the NIDDK Repositories, and hence the NIDDK Repositories will not be able to give out your name or other information that identifies you to the researchers who use your DNA sample and data.

The NASH CRN will be responsible for deciding how it will be used. The specimens collected from you and the DNA that they contain may also be used in additional research to be conducted by the University of California personnel collaborating in this research. These specimens, DNA, and their derivatives may have significant therapeutic or commercial value. You consent to such uses.

If you do not agree to have your blood sample sent to the NIDDK Genetics Repository to obtain and store DNA, you may still participate in the FLINT Trial. If you agree now but change your mind later about having your sample and data sent to the Repositories, you may withdraw unused DNA sample during the study but data already collected from analysis of your DNA sample will continue to be used.

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 a number and code that cannot be linked to your name 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 donate blood for this genetic study. If you decide to donate blood, you may withdraw or modify your consent at any time during the FLINT Trial. If you decide to withdraw your consent entirely, your DNA 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.

If you decide to donate blood for genetic research, you may give permission for using your DNA sample for any or all of the purposes below:
(1) Genetic research on NASH that is currently planned by the study investigators,
(2) Future genetic research on NASH by this study or other study investigators,
(3) Future genetic research unrelated to NASH by this study or other study investigators.

COSTS

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

COMPENSATION

There will be no additional compensation for donating your blood for this genetic study.

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 genetic research study.

Please read each sentence below and think about your choice. Please check either Yes or No for each of the three items and then sign your name below.

1. I agree to donate blood for obtaining DNA for **genetic research on NASH that is currently planned by the study investigators**.
Yes ____ No ____

2. I agree to donate blood for obtaining DNA for **future genetic research on NASH by this study or other study investigators**.
Yes ____ No ____

3. I agree to donate blood for obtaining DNA for **future genetic research NOT related to NASH by this study or other study investigators**.
Yes ____ No ____

If you do not want to donate blood for current or future genetic research, you should be sure to have checked No to all three questions above.

_____ _____
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.