University of California, San Diego

Nonalcoholic Fatty Liver Disease (NAFLD) Adult Registry

Collection, Storage, and Use of Blood Samples for Current and Future Genetic Research

Informed Consent Statement
(Adult Consent)

Dr. Rohit Loomba is asking you to participate in genetic research because you have consented to participate in the NAFLD Registry research study. If you give permission, a sample of your blood will be used as a source of DNA (the genetic material inside your cells) to study the genetic reasons for NAFLD and NASH-related cirrhosis. Also, some of your sample will be saved for future genetic research related to NAFLD or NASH-related cirrhosis and also for future research that may not be related to NAFLD or cryptogenic cirrhosis.

If this consent statement has words that are unclear, please ask the study doctor or other study staff to explain. You are entitled to have any questions about the genetic research answered to your satisfaction. Before making your decision, you may think about it at home and to discuss it with your family or friends. If you decide to allow your blood sample to be used for this genetic research, 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.

WHY IS THIS STUDY BEING DONE?

It is thought that several genetic factors contribute to NAFLD and NASH-related cirrhosis. If you agree to take part in this genetic study, your genes will be studied to identify a relation between NAFLD or NASH-related cirrhosis and certain parts of DNA. In the future, this research may provide doctors with alternatives to liver biopsy for the diagnosis of NAFLD and for monitoring the progression of NAFLD. This genetic research may also help researchers to develop drugs for the treatment of NAFLD and NASH-related cirrhosis.

WHAT MAKES THIS DIFFERENT FROM OTHER SAMPLES COLLECTED IN THE NAFLD REGISTRY STUDY?

Please note that this blood sample, which will be used as a source of DNA, is in addition to the blood samples which you consented to provide and have banked when you consented to participate in the NAFLD Registry study. Those samples will be processed for serum and plasma. This consent document 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 study and still participate in the NAFLD Registry study.

DNA BANKING

Your DNA specimens will be kept in a bank for research related to the NAFLD Registry study and other research in the future. Dr. Loomba will be responsible for deciding how your specimens will be used. The specimens collected from you and the DNA that they contain may also be used by University of California personnel collaborating in this research. Your DNA or the information from it may be used by

other scientists for additional research in the future. These specimens, DNA, and their derivatives may have significant therapeutic or commercial value. You consent to such uses.

If you do not agree to participate in the genetic research component of this study, you may still participate in the NAFLD Registry.

Your DNA specimen will be kept for a duration of 20 years.

The research done on your DNA in this study is not genetic testing. Genetic testing means having a proven test performed in a lab with a special type of certification and the results provided to you and your doctor to make decisions about your health care. If you are interested in having genetic testing performed you should consult your doctor, as some commercial tests are available. Your doctor can provide you with the necessary information to determine if such a test would be appropriate for you. Since this research is not genetic testing, the results of research done on your specimens will not be provided to you.

Sometimes research results in findings or inventions that have value if they are made or sold. There is no plan to compensate you if this happens.

PROCEDURES

If you decide to donate your blood, we will draw about one tablespoonful of blood from your forearm veins at the second screening visit. Your blood sample will be stored at the University of California at San Diego where DNA will be obtained from your blood sample.

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. If numbing cream is used for blood draws, it may cause pain, skin irritation, or the skin temporarily turning red, white or developing a rash. This usually doesn't last very long.

General risks: There is a potential risk to your confidentiality. 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.

Unforeseeable risks:

Although serious injury to organs or death has not been attributed to blood draws, it is possible that currently unforeseen side effects, including serious injury to organs or death may occur. Also, because this is an investigational study, there may be some other unknown risks that are currently unforeseeable. The subject will be informed of any significant new findings.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There are no direct benefits to you. Research conducted on your DNA may help researchers to better understand NAFLD and other health conditions afflicting humankind.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you should contact Dr. Loomba.

If you agree to participate in this genetic research, but decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Loomba, who will make his best efforts to stop any additional studies if any of your specimen has not yet been used up. However, in some cases, such as if your specimens have had information linking your identity to the specimen removed, this may not be possible.

If you decide to donate blood for genetic research, you may give permission for using your DNA for any or all of the purposes below:

(1) Genetic research on NAFLD or NASH-related cirrhosis that is currently planned by the study investigators,
(2) Future genetic research on NAFLD or NASH-related cirrhosis by this study or other investigators,
(3) Future genetic research not related to NAFLD or NASH-related cirrhosis by this study or other investigators

You will indicate your wishes later in this document.

WHAT ARE THE COSTS?

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

WILL I GET COMPENSATED?

There will be no compensation for your participation in this genetic study.

WHAT IF I AM INJURED IN THE STUDY?

If you are injured as a direct result of participation in this research, the University of California will provide any medical care needed to treat those injuries. The University will not provide any other form of compensation to you if you are injured.

You may call the Human Research Protections Program Office at (858) 455-5050 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

WHAT ABOUT 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 personnel at this site. The samples 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. If results from this study are published in medical literature, you will not be identified by name. Representatives from the United States Food and Drug Administration (FDA) or the Institutional Review Board at this clinic may review your records, including your medical records.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Loomba or _____ have explained this study to you and answered your questions. If you have other questions or research-related problems, please call: Thu Nguyen at 619-543-5459

After Hours:

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

SIGNATURE AND CONSENT TO BE IN THE STUDY

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

1. I agree to donate blood for obtaining DNA for **genetic research on NAFLD or NASH- related cirrhosis that is currently planned by the study investigators**.
   Yes ____ No ____
   Initials _____

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

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

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.

_____ _____ _____

Subject's signature Witness Date

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.