University of California, San Diego

Nonalcoholic Fatty Liver Disease (NAFLD) Adult Database 2

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

Informed Consent Statement
(Adult Consent)

STUDY INVESTIGATOR AND SPONSOR

Drs. Rohit Loomba and Heather Patton are asking you to donate your blood sample for genetic research because you have or are suspected to have NAFLD or NASH-related cirrhosis and you have consented to participate in the NAFLD Database 2 research study. If you give us permission, a sample of your blood will be used as a source of DNA 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, 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 sample, we will ask you to give your consent by signing in the space provided below. The study staff will cosign 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 DATABASE 2 STUDY?

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 NAFLD Database study. Those samples will be processed for serum and plasma. 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 NAFLD Database 2 study.

PROCEDURES

If you decide to donate your blood, we will draw two tablespoonfuls of blood from your forearm veins at the second screening visit. Your blood sample will be sent to the NIDDK Genetics Repository 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. You will have no financial gain if you take part in this genetic study.

DNA BANKING

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 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.

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

The Repositories are a research resource supported by the NIH. The Repositories collect, store, and distribute DNA and study data from people with many kinds of disorders, from unaffected family members, and from other healthy people. The purpose of this collection is to make DNA and data available for use in health research. Your DNA and data will be used by the researchers carrying out the NAFLD Database, but they also may be used by other researchers, both during the study and after it ends. Your DNA and data may be stored indefinitely.

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

If you do not agree to have your blood sample sent to the Genetics Repository to obtain and store DNA, you may still participate in the NAFLD Database 2. If you agree now but change your mind later about having your sample and data sent to the Repositories, you may withdraw unused DNA during the study but data already collected from your DNA tests will continue to be used.

Because researchers will not have access to your identity, you will not get the results of any studies that might be performed on your DNA. 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.

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 staff at this clinic. Your health and medical information will be sent to the Data Coordinating Center currently 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, which will allow us to resist any demands for your health information, with a few exceptions as explained below. The Certificate protects us from being forced to disclose information that may identify you, even if by a court subpoena. We are also protected from demands for your information made by federal, state, 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 U.S. Food and Drug Administration. The Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in the research. If an insurer, employer, or other person obtains your written consent to receive research information, then we may not use the Certificate to withhold that information. Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse or neglect or a risk of harm to yourself or others, we are required to notify the proper authorities.

You or your doctor will not receive any results obtained from the DNA research except in a very rare situation where the researchers decide that a specific test result would provide important information for your health.

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 freely withdraw or modify your consent at any time. If you decide to withdraw your consent entirely, any leftover DNA will be destroyed. Your decision will not change your participation in the NAFLD Database 2 study nor will it change future medical care at this institution.

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

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 TO DONATE BLOOD FOR THIS GENETIC STUDY?

There will be no additional compensation for donating your blood for this genetic study as it is part of the second screening visit which you will be compensated for.

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.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Drs. **Loomba, Patton 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.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Participation in research is entirely voluntary. You may refuse to participate or decide to stop participating at any time without jeopardy to the medical care you receive. If you do participate, you may freely withdraw from the study at any time. Your decision will not change your future medical care at this site or institution. The study doctor or the sponsor may stop your participation in this study at any time without your consent. The reasons may include: the study doctor thinks it is necessary for your health and safety, you have not followed study instructions, the sponsor has stopped the study, or administrative reasons require your withdrawal. If you decide that you no longer wish to continue in this study, you will be required to sign a document stating your intent. Please contact the study coordinator or the Investigators to express your intent. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about your rights, or to report research related problems, please contact:

University of California, San Diego
Human Research Protections Program
(858) 455-5050

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means that you have read the above information about the purpose of the study and the potential benefits and risks of participation in the study. You have had an opportunity to discuss it with Dr. _____ or other involved investigators and to ask questions about the study procedures. All of your questions have been answered to your satisfaction. All oral and written information and discussions about the study are in English [or in a language in which you are fluent].

Your signature below indicates that you 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 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.

_____
NAME OF SUBJECT

_____ _____
SIGNATURE OF SUBJECT DATE
(An acceptable representative, if legally applicable, can be substituted for the patient's printed name, date, and signature.)

_____
NAME OF PERSON WHO EXPLAINED THIS FORM

_____ _____
SIGNATURE OF PERSON WHO EXPLAINED THIS FORM DATE
I, the undersigned, have fully explained the relevant details of this study to the patient named above (and/or the subject's legally acceptable representative), and will provide him/her with a copy of this signed and dated informed consent form.

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.