National Institutes of Health (NIH)

Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN)

Nonalcoholic Fatty Liver Disease (NAFLD) Database

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

INFORMED CONSENT STATEMENT

Introduction

We ask you to donate your blood sample for genetic research because you have or are suspected to have NAFLD or cryptogenic cirrhosis and you have consented to participate in the NAFLD Database 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 cryptogenic cirrhosis. Also, some of your sample will be saved for future genetic research related to NAFLD or cryptogenic 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.

Purpose

It is thought that several genetic factors contribute to NAFLD and cryptogenic cirrhosis. If you agree to take part in this genetic study, your genes will be studied to identify a relation between NAFLD or cryptogenic 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 cryptogenic cirrhosis.

Difference from Other Samples Collected in the NAFLD Database 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 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.

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 NAFLD and other health conditions afflicting humankind. You will have no financial gain if you take part in this genetic study.

DNA Banking

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. 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.

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 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 cryptogenic cirrhosis that is currently planned by the study investigators,

(2) Future genetic research on NAFLD or cryptogenic cirrhosis by this study or other investigators,

(3) Future genetic research not related to NAFLD or cryptogenic cirrhosis by this study or other investigators.

Questions

In the future, you may have questions about your study participation. If you have questions, contact [STUDY PERSONNEL contact info].

If you have questions about your rights as a research subject, you may contact [IRB contact info].

Consent

I have read the above information about the purpose of the study and the potential benefits and risks of participation in the study. I have had an opportunity to discuss it with Dr. _____ or other involved investigators 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 NAFLD or cryptogenic cirrhosis that is currently planned by the study investigators**.

   Yes ____ No ____

2. I agree to donate blood for obtaining DNA for **future genetic research on NAFLD or cryptogenic cirrhosis 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 NAFLD or cryptogenic cirrhosis 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)

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

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.

_____ _____
Person obtaining consent (printed name) Date

_____
Person obtaining consent (signature)

_____ _____
Witness (printed name) Date

_____
Witness (signature)

_____ _____
Investigator (printed name) Date

_____
Investigator (signature)