



## University of California, San Diego

### Colesevelam versus placebo in the treatment of nonalcoholic steatohepatitis

#### 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, Heather Patton, Yuko Kono and Benjamin Cohen are asking you to donate a blood sample for genetic research because you have or are suspected to have Nonalcoholic Steatohepatitis (NASH) or are a participant in the control group and you have consented to participate in the *Colesevelam versus placebo in the treatment of nonalcoholic steatohepatitis* 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 NASH and Nonalcoholic Fatty Liver Disease (NAFLD). Also, some of your sample will be saved for future genetic research related to NASH, NAFLD and also for future liver research that may not be related to NAFLD.

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 spaces 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?**

Genes are inherited and direct the growth, development and functions of your body. For example, some genes control the color of your hair or eyes. Cells in your body contain a type of molecule called deoxyribonucleic acid, or DNA for short. DNA is what your genes are made of. There are many differences, or variations, in DNA from one person to another. These variations may affect a person's chance of suffering from a particular disease or the way a person responds to a particular drug.

The blood samples collected for DNA information will be used to analyze the way genes may relate to 1) how investigational therapies are absorbed, broken down and eliminated from the body, 2) how they affect the body and 3) how DNA relates to human disease.

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

#### **WHAT MAKES THIS DIFFERENT FROM OTHER SAMPLES COLLECTED IN THE COLESEVELAM VS PLACEBO NASH STUDY?**

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 Colesevelam vs Placebo NASH 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 *Colesevelam versus placebo in the treatment of nonalcoholic steatohepatitis* study.

## **PROCEDURES**

If you decide to donate your blood, we will draw two tablespoonfuls of blood from your forearm veins at one of the 6 study visits. Your blood sample will be kept in a secure location in the UCSD Medical School Basic Science Building.

## **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 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.

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

## **DNA BANKING**

Your specimens (serum, plasma, stool and liver tissue) collected as part of this study will be stored and kept locked in the UCSD Medical School Basic Science Building and only Dr. Loomba or his research associates will have access to them. Because researchers will not have access to your identity, you will not get the results of any future 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. You consent to such uses. Your DNA and data may be stored indefinitely.

## **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. 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. You or your doctor will not receive any results obtained from the DNA research. When results from this study are published in medical literature, you will not be identified by name.

As part of the ongoing monitoring of the Study for safety and or legal reasons, representatives from the United States Food and Drug Administration (FDA) or the UCSD Human Research Protection Program may review your records, including your medical records,

### **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 Colesevelam vs placebo NASH 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 NASH and NAFLD that is currently planned by the study investigators,
- (2) Future genetic research on NASH and NAFLD by this study or other investigators,
- (3) Future genetic research not related to NASH and NAFLD 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 the blood draw will take place at one of the study visits for which you are already being compensated.

### **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 UCSD Human Research Protections Program office to inquire about your rights as a research subject or to report research-related problems at (858) 455-5050.

### **WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

Drs. Rohit Loomba, Heather Patton, Yuko Kono, Benjamin Cohen or \_\_\_\_\_ have explained this study to you and answered your questions. If you have other questions or research-related problems, please call: Jennifer Patterson at 858-534-0950.



After Hours: UCSD Hospital Operator at 619-543-6737 – Ask the operator to page Drs. Rohit Loomba, Heather Patton, Yuko Kono or Benjamin Cohen. 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. 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 \_\_\_\_\_ 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. You agree to donate blood for obtaining DNA for **genetic research on NASH and NAFLD that is currently planned by the study investigators.**

Yes \_\_\_\_ No \_\_\_\_

2. You agree to donate blood for obtaining DNA for **future genetic research on NASH and NAFLD by this study or other study investigators.**

Yes \_\_\_\_ No \_\_\_\_

3. You agree to donate blood for obtaining DNA for **future genetic research NOT related to NASH and NAFLD 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.



\_\_\_\_\_  
NAME OF SUBJECT

\_\_\_\_\_  
SIGNATURE OF SUBJECT

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

\_\_\_\_\_  
DATE

\_\_\_\_\_  
NAME OF PERSON WHO EXPLAINED THIS FORM

\_\_\_\_\_  
SIGNATURE OF PERSON WHO EXPLAINED THIS FORM

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.

\_\_\_\_\_  
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

