INFORMED CONSENT FORM

Official title: The Genetic, Protein, and Lipid Basis of Variation in Cholesterol Efflux

NCT number: NCT04061018

IRB Approved date: 10-07-20

The University of Texas Southwestern Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	The Genetic, Protein, and Lipid Basis of Variation in Cholesterol Efflux
Funding Agency/Sponsor:	National Institute of Health
Study Doctors:	Anand Rohatgi, MD

You may call the study doctor or research personnel at 214-645-7500.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- If you are not scheduled to undergo a procedure for clinical reasons, you must be an adult with the capacity to give consent in order to provide blood or spinal fluid.
- During the study we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

Why is this research being done?
The purpose of this study is to start an electronic database for patient information and to collect blood from people whose blood has a very low or very high ability to remove cholesterol from cells. We are also collecting information and samples from their relatives.

We are collecting these samples and medical information so that they can be made available to research scientists who are involved in the study of these diseases. This research is attempting to improve upon our ability to diagnose these conditions.

How many people will take part in this study?
About 500 people will take part in this study at UT Southwestern.

What will happen if you join this study?
If you agree to be in this study, we will ask you to do the following things:

Medical Record Review: Your medical records will be reviewed by a member of our team and selective data will be entered into a secure electronic database. This will include your history and treatment that will make your samples even more useful to the research community. This information will include demographic information (race, ethnicity, gender, age), family history, and other pertinent results or information.

Medical records will be reviewed on a regular basis to ensure up to date data.

Pedigree: You will be asked about your family and a pedigree (family tree) will be created.

Samples of Blood: Up to 15 teaspoons of blood will be drawn from a vein in your arm with a small sterile needle. This is the standard method used to obtain blood for routine hospital tests. If necessary, the blood draw may be completed in two visits. We may ask for another blood sample if the research laboratory cannot process the first sample. DNA, plasma, serum and cells will be isolated from your blood sample.

For identification purposes, you will be assigned a coded identifier and will not be personally identifiable. This code will be placed on all the material that is sent to the research laboratories.

Data about your medical history, portions of samples and results of tests may be shared with national and international research partners and may be entered into secondary national and international databases. The sharing of this information is meant to increase collaborative projects and bolster worldwide research efforts. The information provided to them will not include your name, medical record number or unique identifiers. It may include your age, date of birth, city of residence or dates of tests.

What will happen to the samples collected for this research?
Dr. Rohatgi will compare information about the health of participants with the results of research tests using their blood, cells, and DNA.

Your blood sample will be used to isolate DNA for genetic analysis. Part of your blood sample may also be used to grow a long term cell line. This immortalized cell line will be stored in a Cell Bank and will be available for research, both now and in the future. This also allows us to perform many tests without having to ask you for additional blood.

Will I be contacted again in the future?
Yes, you may be contacted if updated medical information is needed for the database.

I am willing to be contacted in the future so that follow-up information may be obtained from me.

_____I Agree _____I Decline

Also, if new information becomes available during this study that would make you eligible to participate in other research studies you will be contacted and provided with more information, as well as given the opportunity to consent to participate in those studies at that time.

I am willing to be contacted regarding participating in other research studies in the future.

_____I Agree _____I Decline

Will my specimen be stored for future use?
Yes, your blood specimens will be evaluated by research scientists studying various heart diseases. Some portion may be frozen or stored indefinitely for this future use. Stored specimens may be analyzed in the future using additional technologies without you being asked to sign another consent form.

Will my samples be used to study any other diseases besides my condition?
Yes. An important part of this research is to allow for associations to be made between different diseases. Your sample may be used for broad-based research for a variety of disease states.

Will my sample be used for genetic research?
Yes. Genetic research is an important part of the investigation into the causes of these diseases. The causes of many of these diseases are believed to be the result of combinations of inherited genes and possible various exposures to the environment. Genetic research is an important part of the investigation into the causes of these diseases. There are no plans to inform you, or your relatives, about the results of genetic studies, since at this time the information is not thought to be medically useful.

What is DNA?
DNA means *deoxyribonucleic acid*. DNA is the substance in our cells which contains information we inherited from our parents and other family members. Your DNA contains “genes” which predict things like physical characteristics (eye color, hair color, height, etc.) and may also be a factor in whether you develop or are at risk of developing certain illnesses or disorders.

How is DNA obtained? Cells from blood or other body materials are processed in a laboratory that has special equipment that can extract DNA and identify genes.

What are the risks or discomforts of the study?
There is a risk that your personal health information could be seen by people not working on the study.

- **Questions:** We will ask you questions about your health. However, you can skip any question that makes your uncomfortable.
- **Risks of Blood Drawing:** Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting are also possible, although unlikely. If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researcher staff right away. Telephone numbers where they can be reached are listed on the first page of this consent form.
- **Stress:** You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you.
- **Unforeseen Risks and New Information**: There may possibly be risks to your participation in this research which Dr. Rohatgi does not know about now. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.
- **Loss of Confidentiality:** Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. For more information, please see the section called “Will my information be kept confidential?”

Genetic Informational risks
This research study includes genetic testing. Human tissue contains genes that determine many of a person’s physical characteristics, such as the color of eyes and hair. In some cases, genetic testing of tissues can be used to indicate a risk for the development of certain diseases. Genetic information is unique to each individual and could potentially be used to discover possible changes in a person’s future health status or life expectancy, or that of his/her children and family members.
Releasing this information to you could cause psychological distress, anxiety or family problems. Releasing this information to others, such as including it in your medical record, may pose a possible risk of discrimination, or increase difficulty in obtaining or maintaining disability, long-term care, or life insurance.
These risks would occur if your information is released by mistake. The measures being taken to protect your privacy are discussed below and make this possibility unlikely.
Even though the results of genetic testing may not be linked to you, it is possible that people of your ethnic background may be found to be at more risk for certain diseases based on future genetic research and this information might harm you in the future as a member of the group. Also, there may be unknown risks of genetic testing in the future.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

Are there benefits to being in the study?
There will be no direct medical benefit to you. Since it is possible that the causes of one, some or all of the ability to remove cholesterol from cells could be determined because of research using your samples, someone may benefit in the future.

What are your options if you do not want to be in the study?
You do not have to join this study. If you do not join, your care will not be affected.

Will it cost you anything to be in this study?
No.

Will you be paid if you join this study?
Yes, you will be given a $35 gift card at the end of the study visit. We will pay for your parking expenses and you will be reimbursed additional $35 to cover for your transportation cost to and from the research center if the research visit takes place on the UT Southwestern Medical Center campus. There are no funds available to pay for lost time away from work and other activities, lost wages, or child care expenses.

Can you leave the study early?
Yes. You may withdraw your consent by contacting your study doctor, Dr. Rohatgi at 214-645-7500. However, samples that have been already used for research, as well as any results or information already collected before you withdraw from the study, cannot be destroyed. Refusing to take part in the future will not affect your current or future medical care in any way. If you withdraw from this study at any time, we will stop contacting you.

Will my information be kept confidential?
Information about you that is collected for this research study will remain confidential unless you give your permission to share it with others, or as described below.
You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

To help us further protect the information the investigators have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and helps researchers protect your privacy. This Certificate does not mean the government approves or disapproves of our project.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, that legally require disclosure, such as:

- to DHHS for audit or program evaluation purposes;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The researchers will not, in any case, disclose information about you or your participation in this study unless it is required by law (as mentioned above). The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

What will happen if I am harmed as a result of taking part in this study?
Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas.

You retain your legal rights during your participation in this research

What happens to Data, Tissue, Blood and Specimens that are collected in the study?
Researchers at UT Southwestern work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both UT Southwestern and any sponsor of this research may study your data and the tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, UT Southwestern may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Rohatgi at 214-645-7500.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time