Informed Consent Form Cover Page

Title: Familial Hyperlipidemia Family Registry

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Consent and Authorization Form

Principal Investigator: Gary Luckasen, MD
IRB #22-1979

Title: Familial Hyperlipidemia Family Registry

A member of your family has been identified as having a gene variant related to familial hyperlipidemia (high cholesterol). You (and/or your child) are being asked to participate in this study to identify whether you have this genetic variant. If you have the genetic variant, you may be at higher risk for premature heart disease. If identified, the condition can be treated.

Why is this study being done?
This study is identifying people who have a genetic abnormality that causes increased risk of heart disease. Since this condition is inherited, if there is one family member with the condition, it is likely that other members of the family may also have it. People who have this genetic abnormality can be treated with medication to lower their cholesterol.

What happens if I join this study?
If you (and/or your child) join the study, you will be able to have a free genetic test and lipid profile to learn if you have the gene for high cholesterol. The lipid profile will be performed via a finger stick blood sample and will measure your cholesterol and triglycerides. The genetic test for the familial hyperlipidemia gene will be performed via a cheek swab (buccal swab). If you have already had the free genetic test performed at any time point or the lipid panel within the last year, you have the option to allow us to utilize your results to be included in this study.

Your lipid and genetic results will be included in a database with other family members. Data collected in this study will help identify family members who might have the genetic abnormality. Your data will be de-identified and not shared with other family members. All identifying data will be removed when used for any presentations or publications.

You will have the option to be referred to a specialist who treats cholesterol disorders.

Your results will be explained to you by the research team. Invitae genetic counselors will be available for scheduled discussions about the condition.

What are the possible discomforts or risks?
There are no significant risks from this study. In this study we will need to get a few drops of blood from your (and/or your child's) finger. To do this, we will make a small prick on your finger and draw the blood into a tiny tube. You will feel a slight pain when the needle pricks your finger. Your fingertip may be sore for a day or two. There is a risk that people outside of

the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?
You and your family may benefit by learning that you have the genetic variant that causes increased cholesterol and may lead to higher risk of heart disease. This can be treated early and possibly lower your risk of developing heart disease. A family tree can be used to track inheritance of the genetic variant to potentially identify and protect future family members.

Who is paying for this study?
This research is being paid for by UCHealth as a community benefit.

Will I be paid for being in the study?
You will not be paid to be in the study. However, you and your participating family members will receive a free genetic and lipid test and access to staff for consultations on the genetic results.

Will I have to pay for anything?
Participating in this study will be free of cost for you and your family.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?
You may be removed from the study at any time under the discretion of the study staff and Principal Investigator.

What happens if I am injured or hurt during the study?

- If you have an injury while you are in this study, you should call Healthy Hearts and Minds immediately. Their phone number is 970-624-1589.

- We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?
The researcher carrying out this study is Gary Luckasen, MD. You may ask any questions you have now. If you have questions later, you may call Dr. Luckasen and the Healthy Hearts and Minds staff at (970) 624-1589. You will be given a copy of this form to keep.

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You may have questions about your rights as someone in this study. You can call Dr. Gary Luckasen and the Healthy Hearts and Mind staff with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724- 1055.

Who will see my research information?

UCHealth, The University of Colorado Denver | Anschutz Medical Campus (the University), and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: UCHealth.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. 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.

Dr. Gary Luckasen
UCHealth Healthy Hearts and Minds Research
3855 Precision Dr. Suite 180, Loveland, CO 80538

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research.
- The study doctor and the rest of the study team.

- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.
- Invitae, the company performing the genetic testing and counseling.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to: Invitae, the company performing the genetic testing and counseling.

Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information will not be released to others.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Tissue samples and the data with the sample.

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Genetic Information Nondiscrimination Act (GINA)
A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health 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 that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.
- Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Future Research
The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____

Print Name: _____

Date: _____

Consent form explained by:

Signature: _____

Print Name: _____

Date: _____

I agree to give my child permission to participate in the study.

Child's name to be enrolled in the study _____

A signature of a child participant between 13-17 years old who can read this form.
The parents are consented using this form above.
If child is under 13 years old the Assent Form will be signed by the child.

Signature: _____

Print Name: _____

Date: _____

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Signature: _____

Print Name: _____

Date: _____

Check applicable box below.

Witness of Signature ☐
Witness of consent process ☐