Protocol Title: Leveraging behavioral economics to equitably implement cascade screening in individuals with familial hypercholesterolemia in partnership with the Family Heart Foundation

NCT05430191

Document Date: October 18, 2022

RESEARCH SUBJECT INFORMED CONSENT FORM

Protocol Title:	Leveraging behavioral economics to equitably implement cascade screening in individuals with familial hypercholesterolemia in partnership with the Family Heart Foundation (Post Pilot Interviews)
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study because either you or your family member participated in a small pilot program to improve cascade screening in family members of patients diagnosed with familial hypercholesterolemia, also referred to as FH. We would like to interview you to hear about your experience with this program.

Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the University of Pennsylvania Institutional Review Board (IRB) at (215) 898-2614 for assistance.

If you agree to join the study, you will be asked to participate in a one-time interview either over the phone or via videoconference. The interview will last 15-30 minutes. We may also contact you in the future to ask if you are interested in participating in additional activities related to this research.

You will be compensated $25 for your time in the form of a virtual debit-like card called a ClinCard.

The most common risk of participation is feeling uncomfortable. You can choose not to participate in this study and your choice will in no way affect the care you or your relatives receive at Penn Medicine.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you or your family member participated in a small pilot program to get screened for FH.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to provide your consent verbally, and we will offer to send a copy of the consent form to you for your records.

What is the purpose of this research study?

The purpose of this study is to hear about your experience with a small pilot program to help people get screened for FH.

How long will I be in the study?

If you agree to join the study, you will be asked to participate in a one-time interview either over the phone or via videoconference. The interview will last 15-30 minutes.

What am I being asked to do?

If you agree to join the study, we will schedule this interview at a time that is convenient for you. Depending on your preference, we will either send you a link to a videoconference or call you at your preferred phone number. We will review this consent form and confirm that you agree to be audio-recorded during the interview. During the interview, we will ask you questions about your experience with cascade screening and what made it easier or more difficult. We will ask you about your experience interacting with doctors and the healthcare system.

What are the possible risks or discomforts?

Some of the questions we ask you might make you feel uncomfortable, anxious, or frustrated. You may also feel embarrassed, distressed, or inconvenienced. You can choose not to answer a question or stop participating in the interview at any time.

What you say during the interview will be kept private and we will not share it with anyone outside of the research team. However, there is a risk of breach of confidentiality; the research team will make every effort to make sure your privacy and confidentiality is maintained by collecting, recording, and storing data securely.

What are the possible benefits of the study?
There is no benefit to you. However, your participation in the interview will help researchers learn more about the barriers to cascade screening.

What other choices do I have if I do not participate?
Your alternative to being in the study is to not be in the study.

Will I be paid for being in this study?
You will be compensated $25 for your time in the form of a virtual debit-like card called a ClinCard.

Will I have to pay for anything?
You will not need to pay for anything to participate in the interview.

What happens if I do not choose to join the research study?
There is no penalty if you choose not to participate in this interview.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all participants have completed interviews and all the information has been collected. The study may be stopped without your consent for the following reasons:

- You have not followed the study instructions.
- The PI, the sponsor, or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime.

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so.

If you want to stop the interview and withdraw from the study, just let us know and we will stop the interview. If you decide after the interview you do not want your information to be used in this research study, please email us at the addresses on page one of this document to let us know that you want us to destroy the recording and we will delete it immediately.

How will my personal information be protected during the study?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your personal information will only be accessed by the research team at University of Pennsylvania, Northwestern University, Family Heart Foundation, and a professional transcription service. We will not de-identify the audio-recording but will ensure that all transcriptions are de-identified (i.e., no names will be on the transcriptions). We will delete the recordings from the audio recorders after they have been uploaded to a database. We will also maintain your confidentiality by ensuring that identifiable information is masked using numeric codes.

We will maintain your confidentiality by ensuring that:

- Information will only be shared with those working on this study and a transcription service.
- All data reported will be secured using HIPAA compliant technology.
- Participant identity will be masked using numeric codes.
- Data will be entered directly into password-protected files.
- Files kept on the computer will only be identified with participant numbers, and will not contain identifying information.

What may happen to my information collected in this study?

The transcribed interview will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected in this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with one of the Principal Investigators listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

Do you agree to take part in this research study?

☐ Yes ☐ No

Do you want me to email you a copy of this consent form?

☐ Yes ☐ No

[*IF YES*] What is your email address? ____

Name of Subject: ____

Name of Person Obtaining Consent from Subject: ______________________________

Date: ____

Perelman
School of Medicine
University of Pennsylvania

[Today's Date]

Dear [Family Member Name],

I hope this letter finds you well.

My name is [Name] and I am one of [Proband's Name]'s healthcare providers. [OR: Penn Medicine is reaching out to you because]

[Proband's Name] asked me [OR us] to help share some important health information with you that may also affect your health and the health of your other family members.

[Proband's Name] was recently diagnosed with a genetic disorder called Familial Hypercholesterolemia (FH). FH is also known as inherited high cholesterol. Having FH causes high LDL ("bad") cholesterol levels from birth. Having high levels of bad cholesterol puts one at a **higher risk for early heart disease, heart attack, stroke, and possibly even death, *if left untreated*.** Fortunately, there are many effective treatment options available.

As [Proband's Name]'s [Relation to Proband], **it is important to understand your own FH risks and options for next steps.**

FH runs in families. Based on your relation to [Proband's Name], you have a **__% chance** of also having inherited FH. Overall, parents, children, and siblings of people with FH have a 50% chance of also having inherited FH or not. Other family members (aunts, uncles, nieces, nephews, cousins, grandchildren, etc.) may also have inherited this serious genetic disorder.

Since sharing complex health information can be hard, your relative gave me [OR us] your contact information and asked that I [OR we] reach out to you directly to discuss this information.

I [OR A member of our Penn Medicine team] will contact you soon to follow up on this information and discuss with you:

- [Proband's Name]'s FH result.
- What this information means for you.
- Next steps you can take to protect your heart health and the health of your loved ones.

For more information about FH, you can visit the webpage of the **FH Foundation**, a patient-centered organization for FH, at FamilyHeart.org.

If you do ***not*** wish to hear from me [OR us], please contact our team (toll-free) at **NUMBER** or **EMAIL** to let me [OR us] know.

Please feel free to also contact me [OR us] before I [OR we] contact you with any questions or concerns you may have. Otherwise, I [OR we] will talk to you soon!

Sincerely,

[Signature]