The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: **Using pharmacy extenders to optimize ezetimibe as add-on therapy to statins for secondary ASCVD prevention outcomes in a federally qualified**
Principal Investigator: Morgan Stewart, PharmD, BCACP, BC-ADM, CommUnityCare, The University of Texas at Austin College of Pharmacy
Study Coordinators: Madison Tran, PharmD Candidate 2027 and Kathryn Litten, PharmD, BCACP, CommUnityCare, The University of Texas at Austin College of Pharmacy

Invitation to be Part of a Research Study

You are invited to be part of a research study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Feel free to ask if anything is not clear in this consent form.

Overview of Key Information about this Research Study

Things you should know:

- The purpose of the study is to improve care for patients with high cholesterol.
- If you choose to join the study, you will be asked to answer a phone call from study personnel. They will help you coordinate follow up appointments, review your medications and lab with you, and answer any questions you have about your medications. You will also continue to be seen by a clinical pharmacy team member. Your cholesterol medications may change to better lower your cholesterol. We will collect information about your visits, medicines, and cholesterol levels for 6 months.
- If you choose not to participate, you will receive the same information and treatment at your next scheduled visit. You will receive the same care regardless of choosing to participate in the study.
- Participation might involve a very low risk of some loss of privacy. There is low risk that someone outside the research study could see information about you.
- A possible benefit is lower cholesterol.
- Taking part in this research study is your choice. You do not have to participate, and you can stop at any time without any penalty.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this study.

Your Participation in this Study is Voluntary

It is your decision to be in this study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. Your decision not to take part or to withdraw will involve no penalty or loss of benefits.

What is the study about and why are we doing it?

The purpose of the study is to improve care for patients with high cholesterol. Some patients at CommUnityCare are not meeting their cholesterol goals with their current medications. The study team wants to see if using pharmacy helpers, such as a student intern, through telehealth can help more people reach their cholesterol goals and avoid heart problems in the future.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

- Participate in a phone call with a pharmacist student intern about current cholesterol levels and medications
- Schedule and attend an appointment with a clinical pharmacist
- Schedule and complete lab work (a fasting lipid panel) within 4-12 weeks of the first appointment
- Schedule and go to a follow-up appointment with a clinical pharmacist within 4-12 weeks of the first appointment with completed lab work
- Possibly change the strength of your cholesterol medication or add a cholesterol medication
- Follow your medication regimen as recommended

Your part in this study will last up to 6 months. About 1,000 individuals will be part of this study.

What alternatives are available?

If you choose not to take part in the study, you will still receive a follow-up phone call from your clinical pharmacy team. You will keep getting the usual care. You will still have follow-ups from your clinical pharmacy team. The same procedures for prescribing your medicine will be followed at your next visit if you choose not to participate.

What risks and discomforts might you experience from being in this study?

There is minimal risk if you join the study as you will receive the standard care. Everyone will get the same care whether they join the study. A very low risk in taking part in this study might involve some loss of privacy. There is very low risk that someone outside the research study could see information about you. More information about how we will protect your information can be found below.

How could you benefit from this study?

There is no guarantee that you will receive any benefits from being in this study. A possible benefit is lower cholesterol. We hope the information learned from this study will provide more information about how to best help patients lower their lipids levels and avoid future heart problems.

How will information about you be protected?

UT Austin and CommUnityCare have safe databases and computer systems to keep data for this study. These systems help track and run the study. Your information may be kept in these systems. Only people working on this study or those with research that uses health information

from your medical record can affect your privacy. Your participation in this study will be held strictly confidential and only a code number will be used to identify the stored data.

Your personal information will not be shared outside of UT Austin and CommUnityCare unless stated in this consent or required by law. If the results of this study are shared, your name and personal details will not be included.

Your personal information might be shared by the study team to track and run this study. These include:

- People from UT Austin and CommUnityCare, like the Institutional Review Board (IRB). The IRB a group of people in charge of protecting the rights and safety of study participants)
- People from CommUnityCare and UT Austin working on this study

It will be written in your electronic health record at CommUnityCare that you are in this study. This record will include information about the study, like medication or lab work you may have. This information is protected like how your other health records are protected.

A description of this study will be available on http://www.ClincalTrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to the information we collect about you after the study is over?

We will not share any individual results from the study with you. The study data will be kept for more than 6 years after they study ends. Your name and other information that can identify you will be kept secure and stored separately from the research data collected.

In the future, identifiers might be removed from the information you provide in this study. The information could be used for other research studies without asking you for consent again. Future studies can be by this study team or other researchers.

How will your health information be used and shared during the study?

As part of this research study, we will ask you to share identifiable health information with us. We will ask you for access to current information from your healthcare records. New health information may be created. This may come from study tests, procedures, visits, or surveys. This type of information is considered “Protected Health Information” (PHI) and is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record

☐ Information about sexually transmitted diseases	☒ Diagnosis & treatment codes	☐ Discharge summary
☒ History and physical exam	☒ Consultation reports	☒ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☐ Information about mental health
☒ Other physical or mental health information (specify): Medication list		

Where will you get my records?

For this study, we will obtain records from the following healthcare providers:

- CommUnityCare Health Centers

Who will use or share protected health information about me?

CommUnityCare is required by law to protect your health information that can identify you. By signing this consent form, you allow them to use and/or share your health information for this study. The health information listed above may be used by and/or shared with the following parties below. This is to conduct, monitor, and manage the study:

- Principal Investigator and Research Staff
- Clinical Pharmacy Team at CommUnityCare Health Centers
- Institutional Review Board (IRB) of UT Austin
- Government/Health Agencies
- Others as Required by Law

We will only share your information with the people and groups listed above. We cannot guarantee that the people and groups who get your information will not share it with others without your permission. However, this is unlikely. If this occurs, your information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the study ends. It may also expire when there is no need to review, analyze, and consider the data from the study. The authorization ends for whichever is later.

Statement of Privacy Rights

You may change your mind and take back the right to use your PHI at any time. If you revoke this authorization, the researchers may still use or disclose health information. This information

will have already been collected during your part in this study. If you revoke this authorization, you may no longer be allowed to be a part of the study. To revoke this authorization, you must write to the Principal Investigator at Morgan Stewart, 2409 University Ave Stop 1910, Austin, TX 78712 or Morgan.stewart@austin.utexas.edu.

What happens if I don't want to release my protected health information?
If you decide not to release your PHI as described above, you will not be able to take part in this study.

How will we compensate you for being part of the study?

You will not receive any type of payment for your participation.

What are the costs to you to be part of the study?

There are no costs to participate in this study. Your healthcare and medication costs will be based on your insurance/coverage status as per general care.

Can you stop being in the study?

You can stop being in this research study at any time. Leaving the study will not affect your medical care. Tell the study staff or your healthcare provider if you are thinking about stopping or decide to stop. You may contact the Principal Investigator, Morgan Stewart, at morgan.stewart@austin.utexas.edu.

If you decide to stop the study, your data will be deleted immediately. However, you will continue getting your usual care regardless of your study participation.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- The investigator thinks it necessary for your health or safety
- You are found to not be eligible for the study
- You have not followed study instructions
- Other reasons require your withdrawal

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Morgan Stewart
Phone:
Email: Morgan.stewart@austin.utexas.edu

Or

Kathryn Litten
Phone: 512-978-8593
Email: Kathryn.litten@austin.utexas.edu

Or

Madison Tran
Phone: 972-363-3942
Email: Madison.tran@utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

Please contact the following below if you have questions about your rights as a study participant. If you want to talk to someone not a part of the research team, please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about, and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date