Patient Centered HIV Care Model
Statement of Informed Consent

You are being asked to participate in this project because you have HIV. It is your choice if you want to participate in this project. If you choose not to be in this project, you will continue to receive your normal care from your provider. If you choose to be in the project, you can leave the project at any time. Refusing to participate in the project or leaving the project will not result in any penalty or loss of benefits to which you are entitled as part of normal care.

Why we are doing this project?

HIV is the virus that causes AIDS. Your medical provider, Walgreens pharmacies, the Centers for Disease Control and Prevention (CDC), the University of North Texas Health Science Center (UNTHSC) and HealthHIV are working together to create an HIV care program to improve HIV care quality. The program will link Walgreens' pharmacists with your HIV care provider. The purpose is to see if the program helps people stay in HIV care, continue their HIV medications and achieve good HIV outcomes. Your participation will help us learn if the program may improve care for others.

What does is means to participate?

If you agree to participate, you will receive, at no additional cost to you, Medication Therapy Management (MTM) from a Walgreens pharmacist. MTM is a scheduled visit with your pharmacist to talk about your health and your medications. During these MTM visits, the pharmacist will review your current medications. The pharmacist will talk with you about your health history. The pharmacist may contact your HIV care provider to discuss medicines you are taking or need to take. At the end of each of these visits, the pharmacist will give you a plan for taking for each of your medicines. The pharmacist will also inform your HIV care provider about the plan. The pharmacist will discuss how to best take each medicine you are taking. The pharmacist may also give you other helpful information about your medical conditions. The MTM will be provided to you at no additional cost, but you will still be responsible for any costs related to your medicines.

What will we need from you if you agree to participate?

If you choose to be in this project, you must agree to:

- Pick up all of your medications from the Walgreens pharmacy located at (insert project Walgreens' address)
- Keep your regularly scheduled clinic appointments. Clinic appointments will be scheduled at least every 6 months.

- Keep your scheduled MTM appointments at the Walgreens pharmacy located at (insert address here). These visits will be at least every 3 months for up to two years. Each MTM visit will last about 20 – 60 minutes.

If you choose to be in this project, your HIV care provider and Walgreens' pharmacist will:

- look at your medical and pharmacy records
- share information about your medical care and prescriptions
- review all your medications and discuss if changes are needed
- contact you to talk about health and medication changes

What will your HIV care provider and Walgreens pharmacist share with the rest of the team?

We will send information from your medical and pharmacy records to the CDC, UNTHSC and HealthHIV teams. This information will not identify you or be traced back to you. Your identity will be kept private. All shared information will be identified only by a code number and will be kept in a locked file. Only project staff can open that file. We will collect information about your medical care and history such as

- medical history (including mental health)
- medications
- laboratory test results
- alcohol and drug use
- use of medical and social services
- appointments kept with your HIV care provider and Walgreens pharmacist
- identified problems with medications

Do you have to take part?

It is your choice if you want to participate or not. If you choose to take part, you can stop being in the project at any time. If you chose not to take part or decide later to stop, it will not change your relationship with your HIV care provider, Walgreens pharmacist or other pharmacist. You will still get the same healthcare from your HIV care provider. If you chose to continue getting your medicines from Walgreens, you can still pick up your medicines and talk with your Walgreens pharmacist. If you chose to stop or not take part, you may not be able to receive the MTM services without a cost to you. You should ask your pharmacist to know for sure.

What can you expect from us?

Privacy

All information will be treated in a secure manner. Your identity will not be disclosed. Further, all information will be grouped together with other participants so that no one will know what information came from you.

Questions?

About this project, please

- ask the person who gave you this form
- call (local principal investigator) at (phone number).

About your rights, please contact

- the institutional review board (IRB) at **(**the clinic**)** at (phone number).

Participant's Consent Statement

I agree to take part in the project described here. I have read and agree to what is being asked of me in the statement, and all my questions have been answered. I understand that my participation is completely voluntary. I understand that I may withdraw my consent to participate at any time by contacting (local principal investigator) at (phone number).

_____ _____

Signature of Participant Date

_____ _____-

Signature of Witness Date

Participant's Consent Statement to Collect Basic Characteristics

I **do not** agree to take part in the project.

☐ I **do not** agree to take part in the project but **I agree** to allow the project team to record my basic characteristics. This will allow the project team to understand if the people in the project are similar or different to the people who are not in the project. I have been given a list of the characteristics that the team will record.

☐ I **do not** agree to take part in the project and I **do not** agree to allow the project team to record my basic characteristics.

_____ _____

Signature of Participant Date

_____ _____-

Signature of Witness Date