

***Step VII. - Informed Consent:** Conduct informed consent and have patient sign the document.

You are being invited to take part in a research study. This letter provides you with information about this study. You have a right to decide not to take part or to quit this study at any time, without penalty.

WHAT IS THE PURPOSE OF THE STUDY?

This study will test whether pharmacists can help patients manage their high blood pressure, diabetes, and medication use through home visits, group education sessions and telephone counseling. African-Americans, Asians, and Hispanics age 55 and older and live in Houston Housing Authority facilities will be asked to take part in this study.

WHAT SERVICES WILL I RECEIVE?

You will receive telephone and in-home counseling from a licensed pharmacist. During the visit, the pharmacist will ask you questions about your health, review the medicines you take, and teach you how to live healthier. You will also receive two health education classes facilitated by a health educator.

HOW MUCH TIME WILL IT REQUIRE?

You will receive 1 home visit that will last 1 hour. You will also receive 2 phone calls that will last 10 to 20 minutes per call. You will participate in 2 group sessions that will last 45 - 60 minutes. Total study time is less than five hours over a six month period.

WHAT ARE THE BENEFITS?

You will receive medical information and services from a pharmacist and health educator, which may help you improve your high blood pressure and/or diabetes, use your medications correctly, and improve your overall health. You will receive a \$15 gift card at the end of the program for completing the home visit, group education sessions and telephone calls.

WHAT ARE THE RISKS?

You will have little to no discomfort from answering questions. You may have slight discomfort when having your blood pressure taken. There may be mild, temporary pain when pricking the finger to draw blood to measure your hemoglobin A1c levels. Hemoglobin A1c is a blood test to measure your blood glucose (sugar) levels over the past 2-4 months.

There is a chance that your blood pressure or blood sugar may get very high or low while you are in this study. If this happens, you must contact your doctor.

HOW MUCH WILL IT COST?

There is no extra cost for taking part in this study.

WHAT ARE MY RIGHTS?

Taking part in this study will not affect your medical benefits, housing benefits or services. You do not have to answer any questions or get any services that make you feel uncomfortable. **All information you provide will remain confidential.**

WHO WILL TAKE CARE OF ME IF I GET HURT?

If you have any type of pain or discomfort while you are in this study, Texas Southern University is not able to offer money or pay the costs of medical care. You, your insurer, Medicare or Medicaid will have to pay for any care that is needed. The staff of the study can refer you to a local medical facility, if needed.

For more information about the study, call:

Dr. Aisha Morris Moultry
713.313.7553

or

Texas Southern University Institutional Review Board
713.313.4301

This research project has been reviewed by the Institutional Review Board (IRB) of Texas Southern University, study number _____. This study is being funded by the Department of Health And Human Services Office of Minority Health.

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask the researcher listed above. If I have questions about my rights as a research subject, I can call the Texas Southern University Committee for the Protection of Human Subjects at (713) 313-4301 or go to <http://www.tsu.edu/research>. Your signature shows that you have read this consent form and have agreed to take part in this study.

Name of Participant (please print): _____

Name of Staff (please print): _____

Signature of Participant

Date

Signature of Staff

Date