

Your Name: _____

Study ID: _____

A Team Model for Hypertension Care Participant Consent for TEAM Study

Invitation

You are invited to take part in a research study about high blood pressure. Data will be collected or used by researchers from the University of Wisconsin School of Pharmacy, Medical College of Wisconsin, University of Illinois at Chicago, and University of Kansas. You are invited because you take blood pressure medication. A new pharmacy service is being evaluated at selected pharmacies in Wisconsin. o. About 700 patients will take part. Participation is voluntary.

What is the purpose of the study?

The purpose is to see whether a team model of high blood pressure care can help people with high blood pressure keep their blood pressures low. The study is focused on African Americans, because high blood pressure is more common and more serious in this group. The study is called a TEAM study because pharmacists and technicians will work as a team with patients and doctors.

What will this study involve?

A. If you join the study, the researchers will send a letter to your doctor. The letter will inform your doctor about the study and ask about any conditions that may require special care.

B. Pharmacies will be assigned to two groups by chance, like a flip of the coin. If your pharmacy is assigned to Group 1, you will receive the usual pharmacy care and an educational packet about high blood pressure. If your pharmacy is assigned to Group 2, you will receive a new pharmacy service for people with high blood pressure.

C. If you receive the new service, your pharmacy will arrange a 20-minute meeting to talk about any medication problems or concerns you might have. The service will include a free blood pressure check and brief visit with a pharmacist each month. You will receive a card to record your blood pressure and suggestions from your pharmacist. Your pharmacist also will send reports to your doctor as needed. Your pharmacist will tell you to see your doctor immediately if your blood pressures become very high (210/115 mmHg). All study participants will receive medical care and prescriptions from their doctor as usual.

D. Researchers will evaluate the new pharmacy service by asking all study participants to complete a research questionnaire and blood pressure check when they enroll and 6 and 12 months later. The questionnaire will take about 30 minutes. It will ask about your medications, blood pressure treatment, and services obtained.

E. Researchers will review information from your pharmacy and insurance records. This includes information about your medications, blood pressure treatment, and any contact between your pharmacy and doctor during the study. Researchers may contact your insurance carrier about any hospital or emergency room visits, doctor visits, and medications used during the study. All

Participant Initials: _____

information from your pharmacy record will be used for study purposes only and anything that identifies you personally will be removed.

Are there any risks?

We believe the risks to study participants are small. Pharmacy staff members who provide the new service will receive special training. Steps will be taken to protect your confidentiality. All study participants will receive an identification number (ID). To keep the information we collect about you private and secure we will give you a number and use this number instead of your name. Your name and ID number will be kept in a locked file cabinet and only looked at by research team members. Reports will not identify you, your pharmacy, or your doctors.

Are there any benefits?

We cannot guarantee a direct benefit to study participants. However, the knowledge we gain from this study may help improve the care given to patients in the future.

Are there any costs?

There is no cost to being in this study. Your medications will still be paid for by you or your insurance as usual. The only cost to you is the time you will spend on the research questionnaires and blood pressure checks and the time you might spend if you receive the new service.

Will I be paid for participating?

All study participants will receive a \$5 gift card for the screening, a \$20 gift card for the first research questionnaire, \$25 for the 6-month questionnaire/blood pressure check, and \$25 for the 12-month questionnaire/blood pressure check.

What if I change my mind?

Your participation is voluntary. You can stop participating in the study at any time. You have the right to be given answers to your questions about this study. If you have a question about this study, contact researcher listed below. If you have questions about the rights of research study participants, you can contact either the Medical College of Wisconsin Patient Relations Representative at 414- 456-8505 or the University of Wisconsin-Madison Health Center Patient Relations Representative at 608-263-8009.

Authorization: I, _____, have read the above and decide to participate in the research study described above. My signature also indicates that I received a copy of this consent form.

Participant Signature

Date

Name of individual conducting informed consent discussion (*please print*)

Signature of individual conducting informed consent discussion

Signature of Principal Investigator

Date

Bonnie L. Svarstad, Ph.D.
Professor Emerita of Social and Administrative Pharmacy
University of Wisconsin School of Pharmacy, 777 Highland Ave, Madison, WI 53705
Telephone: 608-265-2128; Email: blsvarstad@pharmacy.wisc.edu

Signature of Milwaukee Principal Investigator

Date

Jane Morley Kotchen, MD, MPH
Professor of Epidemiology
Medical College of Wisconsin, 8701 W Watertown Plank Rd, Milwaukee, WI 53226
Telephone: 414-456-8201, Email: jkotchen@mcw.edu

Participant Initials: _____