Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Pro # 00036888

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

We are asking you to take part in a research study called:

Using Bluetooth Home Blood Pressure Monitors with Pharmacist Interventions to Manage Uncontrolled Hypertension in the Community Setting – A Pilot Study

The study is for patients who have high blood pressure.

The person who is in charge of this research study is Dr. Wendy Updike**.** She is called the Principal Investigator. However, other research staff may be involved and can act on behalf of Dr. Updike.

The research will be conducted at the USF Health Morsani Center for Advanced Healthcare in the Family Medicine department, located in Tampa, FL.

This research is being sponsored for by the National Association of Chain Drug Stores (NACDS) Foundation.

Purpose of the study

The purpose of this study is to find out if patients feel comfortable using a Bluetooth-enabled blood pressure monitor at home, and to discover if patients feel comfortable communicating with a pharmacist about blood pressure results through a telehealth appointment. Another goal of the study is to discover if blood pressure readings improve with regular communication between the patient and pharmacist to discuss blood pressure results and diet and exercise recommendations. We hope to use the results from this study to design a larger study in the future. Home blood pressure monitoring and telehealth

appointments with pharmacists have already been used before with other patients.

Why are you being asked to take part?

We are asking you to take part in this research study because you have been previously diagnosed with high blood pressure, and your blood pressure is currently not well controlled. We want to find out if home blood pressure monitoring and pharmacist communication will help people who have high blood pressure. We are also asking you to participate because you:

- Are at least 18 years old
- Are a current patient at the USF Morsani Center in the Family Medicine Department and obtain your prescriptions from Pharmacy Plus.

Please let the person giving you this to read, know if you:

- Easily understand and can speak English
- Have a smartphone

This study includes the use of the Omron 10 Series Wireless Upper Arm Blood Pressure Device which is FDA approved. The blood pressure device connects to Apple Health software, which will send your blood pressure readings to the computer system that your primary care provider and pharmacist use. The study will also use the telehealth platform VSee. Your pharmacists will communicate with you through this HIPAA-compliant platform. HIPAA-compliant means that it protects your privacy.

Study Procedures: What will happen during this study?

If you are interested in participating in the study, you will be scheduled for an initial one-hour appointment to meet with a pharmacist at the Morsani Center. During this visit, the following will occur:

- The study procedures will be explained to you in detail, and the pharmacist will answer any of your questions.
- You will sign the informed consent form if you agree to participate. Once you sign the informed consent, you will receive a copy for your own records.
- You will receive an Omron 10 Series Wireless Upper Arm Blood Pressure Device, and will be trained on how to use it correctly. You will be asked to measure your blood pressure once daily using this device the whole time you are participating in the study (6 weeks). You will be given blood pressure goals, and the pharmacist will discuss what to do if your blood pressure is too high.
- The pharmacist will show you how to use the Apple Health software on your phone.
- The pharmacist will help you sync the blood pressure device to the app on your phone.
- You will be asked to complete a survey. The survey will ask you for basic demographic information. It will assess your current knowledge of blood pressure and your comfort level with checking your blood pressure at home. It will also ask about previous experiences with a pharmacist managing your blood pressure, if any.

Once you begin monitoring your blood pressure at home, the pharmacists will follow up with you once per week. They will contact you through the HIPAA-compliant platform, VSee. Each weekly telehealth appointment will be approximately 20 minutes in duration. During these weekly appointments, the pharmacist will discuss your blood pressure readings with you, as well as any diet and exercise modifications that you can make to improve your blood pressure readings. Of note, home blood pressure monitoring and pharmacist communication via telehealth have all been done before in other studies and are not new, however we are testing how comfortable you feel with these interventions.

After the 6-week study period, you will be scheduled to come back to the Morsani Center to meet with a pharmacist face-to-face again for a 30-minute appointment. During this last visit, you will be asked to complete a survey to describe your experience with the home blood pressure monitor and with the weekly pharmacist telehealth appointments. This survey will be similar to the survey that you will take at the beginning of the study. You will also be asked to return the blood pressure cuff at the final visit. At the end of this final visit, you will be given a $25 gift card for participating in this study.

The total duration of this study will be 8 weeks.

You will continue to receive the same care from your providers regardless of whether or not you choose to participate in the study. If you do decide to participate, you will receive additional care in the form of weekly communication with a pharmacist to discuss your blood pressure readings.

Total Number of Participants

We are seeking 20 individuals to take part in this study at USF.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.
After signing this informed consent document you may decide to no longer take part in this study, for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely.
- If you decide to stop, you can continue getting care from your regular doctor.
- If you would like to stop, please contact Dr. Wendy Updike at (813) 974-8949 for further instructions.

Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

Benefits

The potential benefits of participating in this research study include:

- Better knowledge and control of your blood pressure
- A more trusting relationship with your pharmacist
- Satisfaction with home telehealth

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. A potential risk exists regarding a possible breach in confidentiality of data collected. However, data will be securely stored and only the people who are listed on the study will be able to access this data. We will do everything possible to protect the data

collected. There are no known additional risks to those who take part in this study. However, there may be risks that are currently unforeseeable.

Compensation

You will be compensated with a $25 gift card if you complete all the scheduled study visits and obtain your blood pressure at home every day.

Costs

Costs include travel associated with the two in-person visits at the clinic site. You may park for free in the Morsani patient parking garage, but may choose to valet for an additional cost. These costs will not be reimbursed for your participation in the study.

Conflict of Interest Statement

The investigators have no known conflicts of interest to disclose.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them completely confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP)]
- The USF Institutional Review Board (IRB) and its related staff who has oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.
- The National Association of Chain Drugstores (NACDS)

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. Wendy Updike at (813) 974-8949. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;
- Each research site for this study including the USF Health Morsani Center for Advanced Healthcare.
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.
- Your responses to survey questions including demographic information, comfort with managing your blood pressure, and experience with home blood pressure monitoring and with pharmacist communication.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your

authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Wendy Updike, PharmD, BCPS
For IRB Study Pro # 00036888
12901 Bruce B. Downs Blvd., MDC 30
Tampa, FL 33612

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research

And Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize the use of my health information as outlined above**.** I understand that by signing this form I am agreeing to take part in research. I have received a signed copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent