Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Patient Centered Health Technology Medication Adherence Program for African American Hypertensives

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study is develop a program to help you better control your blood pressure by helping you learn to take your medications properly. You are being asked to participate in this study because you have high blood pressure. The study is sponsored by the National Institutes of Health (NIH). The investigator in charge of this study is Frank Treiber, PhD. Approximately 200 people will take part in this research study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. At your first study visit:
   a. You will have your blood pressure measured. If your blood pressure is high, you will continue with the screening process below.
   b. You will see a video about the medication tray and the home blood pressure monitor devices that you might use in the study.
   c. You will be asked to complete some questionnaires to help determine your knowledge of high blood pressure management, levels of stress, anxiety, and attitudes toward the use of health related electronics like those shown to you.
   d. Your current blood pressure medications will be counted to determine if you have taken all of your medication doses
   e. You will be taught to use a medication tray that tracks your medication dosing.
      i. The tray will securely send information on when you take your medications to the study team.
      ii. The tray will not provide reminders to take your medication.
2. You will return to the clinic about 4 weeks after your first study visit.
   a. You will bring the medication tray and all of its parts to this visit.
   b. You will have your blood pressure measured and complete questionnaires.

c. Your medications will be counted.

d. The study team will determine if you're able to take part in second part of the study. To determine this, the study team will look at

i. if you are unable to take the medication prescribed by your physician correctly for 4 weeks.

ii. if your blood pressures continue to be above that recommended for adults with high blood pressure,

If you have successfully taken your medications as your doctor prescribed, you will not continue into the second part of the study. You will return the pill tray to study staff and your study participation will be complete.

If you are found eligible, you will continue into the second part of the study.

3. Randomization:
If you are found eligible to continue, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice of which group to which you are assigned. The two groups are Group A (Standard Care Group) and Group B (Intervention Group)

a. If you are chosen to participate in Group A (Standard Care Group):

i. You will continue to use the medication tray without the reminder functions

ii. You will also receive daily text messages that provide healthy lifestyle information.

iii. You will receive the standard care that all hypertensive patients receive.

b. If you are chosen to participate in Group B (Intervention Group)

i. You will continue to use the medication tray, now with the reminder functions turned on. Your tray will help you take your medicines properly by beeping, flashing, and even sending you a text message or email if you miss your dose.

ii. You will also monitor your blood pressure at home with a small device (AnD monitor), that the study provides, and links to an app we will load onto your smartphone.

(a) You will take your blood pressure using the monitor and app twice daily at least every third day. The app will automatically record your blood pressure through blue tooth technology (paired with the blood pressure monitor)

iii. If the data from medication tray or the blood pressure device identifies a problem, you will be contacted by the study team who will assist you in correcting the situation. An example of this is if we see you haven't used your tray for greater than 3 days, we may contact you to make sure it is connected properly and that you understand how to use it. We will also contact you if we notice your blood pressure breaches into a dangerous blood pressure zone - >180 systolic blood pressure.

iv. You will receive the standard care that all hypertensive receive.

c. All participants in the second phase of the study (Groups A and B) will wear a portable blood pressure monitor (Ambulatory Blood Pressure-ABP).
   i. You will wear it at home for 24-hours during your regular daily activities the week of your research study visit.
   ii. The monitor will automatically take your blood pressure every 20 minutes (every 30 minutes at night).
   iii. Because you will wear it for 24 hours, you will take the blood pressure monitor home with you when you leave your visit. In order to return the monitor to the research team, you will be provided with a box and shipping label to send the ABP back to us.

4. All participants in the second phase of the study (Groups A and B) will visit the clinic at the Medical University of South Carolina at 1,3 6, 12 and 18 months after the randomization visit. At these visits you will be asked to:
   a. Have your blood pressure and heart rate evaluated
   b. Your medications will be counted.
   c. You will be asked to complete questionnaires.
5. All participants in the second phase of the study (Groups A and B) will be contacted by the study team by phone every 2 to 3 week intervals to ask you to complete an at-home quick medication count.
6. At the month 6 visit:
   a. You will return the medication tray (Groups A and B) and AnD blood pressure monitor (Group B).
   b. Your blood pressure and heart rate will be checked.
   c. Your medications will be counted.
   d. You will be asked to complete questionnaires.
   e. You will wear the ABP monitor for 24-hours and return it using the box and label provided.
   f. Members of Group B may be asked to participate in an interview to offer their suggestions to improve the mHealth medication self-management program.
7. You will return for two visits 12 and 18 months after randomization.
   a. Your blood pressure and heart rate will be evaluated.
   b. Your medications will be counted.
   c. You will be asked to complete questionnaires.
   d. At the 18-month evaluation, you will wear the ABP monitor for 24-hours and return it using the box and label provided.
8. 32 participants in the Intervention group will be asked to volunteer in a focus group. Selection will be based on your overall ability to take your medications and blood pressure measurements on time.
9. **The table below outlines the schedule of the possible study visits:**
10.

Visit #	Name of Visit	Procedures

1	Screening and Enrollment	Screen for eligibility(3 blood pressure measurements), talk through and sign informed consent, HIPAA explanation, surveys, and device explanation
2	Baseline and Randomization	3 blood pressure measurements, fill out surveys, and explain blood pressure monitors and smart phone application
3	1 month visit	Resting Blood pressure measurement and surveys
4	3 month visit	Resting Blood pressure measurement and surveys
5	6 month visit	Resting Blood pressure measurement, surveys, and 24-hr blood pressure monitor
6	12 month visit	Resting Blood pressure measurement and surveys
7	18 month visit	Resting Blood pressure measurement and surveys, and 24-hour blood pressure monitor

C. DURATION

Participation in this study will take about 7 visits over a period of 18 months. The study visits will take approximately 30 to 60 minutes and we will try to coordinate the study visits to occur on the same day as your regular clinic visits.

D. RISKS AND DISCOMFORTS

All precautions will be taken to protect your privacy; however as with any research study there is always some risk of a breech in confidentiality. Every participant will have a 50% chance of being randomized into the attention control group (healthy lifestyle behavior) and it is likely that this group will not learn nearly as much about consistent, timely medication adherence. Thus this group will be less likely to reduce their blood pressure levels as much as the SMASH intervention arm.

E. BENEFITS

There may be no direct benefit to you for participating in the study. If you are in the group that receives the training and the devices that help remind you to take your medications and take your blood pressures, you may benefit from participating in the study by establishing control of your blood pressure and having fewer medical complications than the current standard therapy; however, this cannot be guaranteed.

It is hoped that the knowledge gained from this study will help in the treatment of future hypertensive patients.

F. COSTS

There will be no cost to you as a result of participation in this study.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated with gift cards of different monetary value. At the initial blood pressure screening and enrollment into the 1-month medication adherence monitoring screening, participants will receive a $10 gift card. At the completion of all other visits you will receive a gift card worth $75. The total compensation possible for all visits in the study equals $460.00. *Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.*

H. ALTERNATIVES

You may choose not to participate in this study and there is no penalty for not participating.

I. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

J. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

K. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Frank Treiber, PhD at 843-792-8852. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Signature of Participant Date