PharmText BP

A Pharmacist Intervention for Monitoring and Treating Hypertension Using Bidirectional Texting

Study Protocol

Date: 9/21/2020

Version: 5.0

Principal Investigators:

Barry L. Carter, Pharm.D., Professor Emeritus, Department of Pharmacy Practice and Science, College of Pharmacy and Department of Family Medicine, College of Medicine, University of Iowa

Linnea A. Polgreen, Ph.D., Associate Professor, Department of Pharmacy Practice and Science, College of Pharmacy, University of Iowa

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Protocol Approval Page

Protocol Approval Page

Study Title:	**A Pharmacist Intervention for Monitoring and Treating Hypertension Using Bidirectional Texting**
Version:	**5.0**
Date of Issue:	**9/25/2020**
Study Sponsor:	**National Heart, Lung, and Blood Institute, U.S. Department of Health and Human Services, National Institutes of Health**

The signatures below constitute the approval of the protocol and the attachments and provide the necessary assurances that this trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812). National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

We, the undersigned, have read and approve this protocol and agree on its content.

Linnea A. Polgreen, PhD
Principal Investigator

Linnea Polgreen 10/27/2020
Signature Date

Barry L. Carter, PharmD
Co-Principal Investigator

Barry L. Carter 10/27/20
Signature Date

Protocol Version and Amendment Tracking

Study Title: A Pharmacist Intervention for Monitoring and Treating Hypertension Using Bidirectional Texting

Version Number/Amendment	Approval Date
Original Protocol, Version 1.0	8/3/2019
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Protocol Synopsis

Protocol Title	A Pharmacist Intervention for Monitoring and Treating Hypertension Using Bidirectional Texting
Main Criteria for Inclusion	Clinic measured blood pressure of ≥ 145 mmHg or ≥ 95 mmHg at two previous clinic visits or one previous clinic visit and on the day of enrollment. Previous clinic visit BPs must be within the past 18 months and measured at least 2 weeks apart from each other.
Study Objective	To evaluate whether our scalable SMS approach combined with a pharmacist-based intervention improves BP management and that is cost effective.
Study Design	A single-site, two-arm, single-blind randomized trial
Number of Sites	1 site, 3-4 clinic locations
Study Arms	2 Study Arms a) Intervention Group- Text 7 morning and 7 evening BP values at baseline. Monitored by a study pharmacist for 12 months. Research visits at 6 and 12 months b) Control Group- Text 7 morning and 7 evening BP values at baseline. Research visits at 6 and 12 months
Total Number of Subjects	420
Duration of Study Participation	12 months
Primary Outcomes	Mean difference in systolic blood pressure between the control and intervention groups at 12 months.
Secondary Outcomes	Mean difference in diastolic blood pressure between the control and intervention groups at 12 months. Total number of medication changes (i.e., dose, discontinuation, initiation, etc.) from baseline to 12 months.

	Total cost of medications, time spent by research staff, and clinic visits per patient from baseline to 12 months.
Statistical Design and Power	The analysis will be done on an intent-to-treat basis regardless of the number of reported BP readings or the number of pharmacist interactions with the participant. Our primary outcome will be a comparison of mean SBP values at 12 months. We will use a linear mixed effects model with mean BP at 12 months as the outcome. We will use random effects for clinic and physician nested within clinic to account for practice heterogeneity between clinics and providers. Based on prior work with the CAPTION trial, we expect a mean decrease in SBP of 17.3 (SD = 17.7) mmHg in the intervention arm and a decrease of 11.6 (SD = 18.2) mmHg in the control arm. We expect a difference of 5.65 mmHg between the groups with an expected pooled standard deviation of 17.9 with equal sized groups. In order to have 85% power to detect a difference of 5.7 mmHg or larger decrease in SBP with a Type I error rate of 5% and a standard deviation of 17.9 mmHg, we would need 180 subjects per arm or 360 subjects total. In preliminary work in the CAPTION trial, 13.4% of control subjects dropped out or were lost to follow-up. 14.0% of subjects dropped out of the intervention arm during the first 9 months. In order to retain power after reasonable attrition rates over 12 months, we will recruit an additional 14% in each group to ensure we have at least 85% power. In addition, the sample size should slightly increase to accommodate the interim analyses. This increases our total sample size to 420. One interim analysis is planned after outcome data is received and the results are reported to the Data Safety and Monitoring Board from the first half of the study. The interim monitoring method of Lan and DeMets will be used with O'Brien-Fleming alpha spending function for the interim analyses. Accordingly, type I error rate of 0.00305 for the interim analysis and 0.4695 will be used for the final analyses. The current sample size of 420 patients total accommodates the interim analyses.
Futility Analysis	To be determined by the Data and Safety Monitoring Board

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Abbreviations

AICc	Akaike Information Criterion with Correction
AWP	Average Wholesale Price
BP	Blood pressure
ICER	Incremental Cost Effectiveness Ratio
GCP	Good Clinical Practice
GLM	Generalized Linear Mixed Effects Model
LMM	Linear Mixed Effects Models
RUCA	Rural-Urban Commuting Area
SMS	Short message service
WyBP	What's your BP?

1. Introduction

1.1 Background

Hypertension causes an estimated 395,000 deaths in the US each year: one out of every six deaths. Hypertension is second only to smoking as a modifiable cause of death in the US. Poor blood pressure (BP) control increases the risk of myocardial infarction, stroke and death and is often due to delays in treatment intensification. In our prior work, we demonstrated that a physician-pharmacist collaborative intervention with pharmacists embedded within the medical offices reduced BP and it was cost effective. However, pharmacists spent a considerable proportion of their time obtaining and aggregating patients' home BP measurements. Thus, we have developed a telehealth service called Centralized Healthcare Solutions that has successfully delivered clinical pharmacy services remotely to private physician offices, especially in small medical offices and rural locations. We have also developed an additional mhealth solution called What's your BP? (WyBP), a custom-built bi-directional SMS based (short message service, or texting) platform. WyBP is inexpensive (i.e., does not require investment in smartphone technology, or WiFi), acceptable to a broad range of patients (including the elderly and rural populations), scalable to subject volume observed in busy clinical settings, and easily integrated into typical clinic workflows. In two pilot studies, we demonstrated a high rate of adherence, indicating that patients were willing and able to take home BP measurements and send them to our research team.

This proposal combines our two prior efforts to use remotely located pharmacists and bi-directional texting to improve efficiencies, reduce cost and improve access to a dedicated pharmacist. A major gap in our knowledge is whether the potency of a "virtual" team member can be improved by home BP monitoring with technological support, especially in small medical offices that are unable to employ clinical pharmacists. The goal of this proposal is to evaluate whether our scalable SMS approach combined with a pharmacist-based intervention improves BP management cost effectively. To achieve this objective, we will determine if our intervention leads to decreases in BP; determine if our intervention leads to intensification of therapy; and determine the cost effectiveness of the intervention. At the end of this project, we expect to provide a novel, scalable and cost-effective approach for treating hypertension in rural populations by expanding the feasibility, scalability and dissemination of the Centralized Healthcare Solutions intervention. The intervention has important public health relevance: if this intervention could be implemented broadly in primary care practices and lead to a decrease of 5 mmHg BP, heart-disease deaths could be reduced by 15-20% and stroke deaths by 20-30%.

1.2 Clinical Experience with the Study Intervention

Dr. Polgreen has conducted clinical trials to capture blood pressure (BP) measurement, and she has been involved in observational research in the field of hypertension. She performed the cost effectiveness analysis for Dr. Carter's CAPTION trial. She is also performing the cost analyses for his current NHLBI-funded studies: ICARE and MedFOCUS. In addition, she published a paper on trends in inpatient admissions for HTN. Her previous K-award "Treatment Effectiveness Using Observational Data: Which Method is Best?" was based on HTN treatment using angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers, and she is using multiple statistical and data analytic techniques to determine treatment effectiveness.

Dr. Carter is a certified hypertension clinician (2016-2026). He practiced as a clinical pharmacist faculty member in Family Medicine residency training programs at the University of Iowa (1980- 1988) and Baylor College of Medicine (1988-1991) where he provided physician

education and direct patient management. He also practiced in the pharmacist-managed hypertension clinic at the West Side VA in Chicago (1991-1995). He was a member of the NHLBI Coordinating Committee of the National High Blood Pressure Education Program (1991-2010), and he was a member of the last four national guideline committees (JNC-5, 6, 7 & 8 [renamed the 2014 guidelines]). He also was asked to take the lead on a writing group on thiazides and dysglycemia by NHLBI. He was a member of the NHLBI workshop to develop research strategies to improve BP control in African Americans and another recent workshop to identify research strategies in Federally Qualified Health Centers.

2. Objectives, Aims, and Hypotheses

2.1 Objective

The objective of this study is to evaluate whether our scalable SMS approach combined with a pharmacist-based intervention improves BP management and that it is cost effective.

2.2 Aims and Hypotheses

2.2.1 Aim 1: Determine if our intervention leads to decreases in BP.

2.2.1.1 Hypothesis: Mean systolic BP in the pharmacist-intervention group will be significantly lower than mean systolic BP in the control group at 6 and 12 months.

2.2.1.2 Hypothesis: Mean diastolic BP in the pharmacist-intervention group will be significantly lower than mean diastolic BP in the control group at 6 and 12 months.

2.2.2 Aim 2: Determine if our intervention leads to intensification of therapy.

2.2.2.1 Hypothesis: Participants in the pharmacist-intervention group will have more treatment changes, on average, than those in the control group.

2.2.3 Aim 3: Determine the cost effectiveness of the intervention.

2.2.3.1 Hypothesis: The intervention will be cost effective when compared to the control group.

3. Subject Inclusion/Exclusion Criteria

3.1 Inclusion Criteria

- English or Spanish speaking males and females.
- 21 – 100 years of age.

- Clinic measured blood pressure of ≥ 145 mmHg or ≥ 95 mmHg at two previous clinic visits or one previous clinic visit and on the day of enrollment. Previous clinic visit BPs must be within the past 18 months and measured at least 2 weeks apart from each other.
- Lives in a zip code that is scored as a 4-10 on the Rural-Urban Commuting Area (RUCA) Codes.

3.2 Exclusion Criteria

- Currently pregnant or planning to become pregnant in the next year.
- Upper arm circumference over 50 cm (20 in)
- Prisoner status.
- Unable to provide own informed consent.

4. Study Design

4.1 Overview

The PharmText BP study was funded in September 2019 by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The study is being led by University of Iowa co-principal investigators Dr. Linnea A. Polgreen, Associate Professor of Pharmacy Practice and Science and Dr. Barry L. Carter, Professor Emeritus of Pharmacy Practice and Science and in the Department of Family Medicine.

The goal of PharmText BP is to conduct a study to evaluate whether our scalable SMS approach combined with a pharmacist-based intervention will improve BP management and that it will be cost effective. The entire study will last 5 years and involve recruitment of 420 participants from 3-4 clinics within 35 miles of University of Iowa Hospitals and Clinics. Participating clinics are listed in Appendix 1. All participants will live in areas that are considered rural by Rural-Urban Commuting Area Codes. The study aims to enroll at least 125 participants (30%) who represent minority populations.

All participants will have an initial screening/enrollment/baseline visit, a 2nd visit at 6 months, and a final visit at 12 months with a research intern. Each in-person visit will include research blood pressure measurements (Omron HEM 907-XL), interviews, and medical record review. In addition to the in-person visits, all participants will be provided with a home BP cuff (Omron 5 Series), enrolled in our bi-directional text-messaging platform, WyBP, and asked to submit 7 morning and 7 evening BP measurements via text message following the baseline visit. Text message prompts asking for these BP measurements will stop after the 14 measurements have been submitted, or after 15 days, whichever occurs first. Following the home BP measurements, participants will be randomized to either the pharmacist intervention arm or the texting-only control arm using a randomized block design with random block sizes with stratification according to clinic.

A timeline for the study procedures is provided in Appendix 2.

Key personnel roles for the study are described below:

Key Personnel	
Research Interns	3-5 full time staff members employed by Internal Medicine at UIHC who will recruit participants and collect data.
Research Pharmacists	2-3 clinical pharmacists will provide the intervention and at least 2 are certified hypertension clinicians as designated by the American Society of Hypertension. Pharmacists will provide telephone, text message, and email support for intervention participants and communicate with participant's doctors via the electronic medical record.

4.2 Recruitment/Screening Procedures

Research interns will review the electronic medical record for patients who are scheduled to visit each of the participating clinics. They will screen the record for the past 18 months to ensure that the eligibility criteria are met and that no exclusionary criteria exist (the REDCap screening instrument is provided in Appendix 3). If they are unsure about any of the inclusion/exclusion criteria for a specific patient, they will defer to the medical staff in the clinic.

Inclusion Criteria:

- English or Spanish speaking males and females.
- 21 – 100 years of age.
- Clinic measured blood pressure of ≥ 145 mmHg or ≥ 95 mmHg at two previous clinic visits or one previous clinic visit and on the day of enrollment. Previous clinic visit BPs must be within the past 18 months and measured at least 2 weeks apart from each other.
- Lives in a zip code that is scored as a 4-10 on the Rural-Urban Commuting Area (RUCA) Codes.

Exclusion Criteria:

- Currently pregnant or planning to become pregnant in the next year.
- Upper arm circumference greater than 50 cm (20 in)
- Prisoner status.
- Unable to provide own informed consent.

Once a potential participant has been identified, the research intern will notify the appropriate medical staff that the patient is eligible for the study. If the medical staff confirms that the BP study is appropriate for the patient, they will inform the patient about the study

during the appointment and ask for permission for the research intern to explain the study further. If the patient is interested in learning more, the research intern will either meet with the patient in the exam room, or move the patient to a research-dedicated room, whichever has a lesser impact on clinic flow for that day. The screening questions will be reviewed again with the patient to ensure accuracy (particularly whether or not a female patient is planning to become pregnant in the next year, as that will not be reflected in the medical record).

If a patient indicates that they are not interested in participating in the study at any time, they will be thanked for their time and allowed to leave the clinic.

If all eligibility criteria are confirmed and they wish to participate, the research intern will describe the study, give the patient time to read the consent form, and answer any questions that the patient may have. Specifically, the research intern will explain the following areas of the consent document:

- Purpose of the research study, duration of study participation, and the number of research visits and study contacts (i.e., texting, phone calls, emails) required.
- The study procedures and requirements.
- The risks of the study.
- The voluntary nature of the study. The participant may drop out of the study at any time.
- That their decision to participate or not will have no effect on their relationship with or care from their physician or on the clinical care that they receive.
- HIPAA information: The research team must have access to the participant's medical information and to create medical information in order for the participant to be in the study; the investigators will obtain medical record data for the time period that spans 18 months preceding enrollment until 12 months following enrollment.
- The research-related injury section.
- Contact information that participants can use to reach investigators for study-related issues.

If the patient agrees to participate, they will be asked to sign two copies of the consent form. The research intern will sign the consent forms as the witness. One copy will be given to the participant and one copy will be kept and filed securely in the research team office. The patient will be enrolled in the research study in the electronic medical record via IRB and hospital policy.

Patients may take an unsigned consent form with them to think about participation. They will be given contact information to schedule a follow-up appointment with an intern at a later date if they choose to participate.

Patients may also sign the consent form but schedule completion of other baseline activities for a later date to meet their scheduling needs.

The English and Spanish consent forms are provided in Appendix 4.

4.3 Baseline Visit Procedures

4.3.1 Baseline Data Collection

After the consent form has been signed, the research intern will continue with the other baseline activities. Together, the intern and participant will complete the demographic information that is collected on the Baseline Data REDCap form (Appendix 5).

4.3.2 Blood Pressure Measurement

Trained research interns will measure the participant's blood pressure and document it on the Baseline Data REDCap form (Appendix 5). All measurements will be taken using the Omron HEM-907-XL using the following procedures:

Prepare the Participant:

- Participants should refrain from smoking for 20 minutes prior to the blood pressure measurement.
- The participant should remove all clothing that covers the location of the cuff placement.
- The participant should be comfortably seated in a chair, with the back supported, legs uncrossed and flat on the floor, the arm supported at heart level on a desk, with the palm facing upward.
- The participant should sit for at least 5 minutes before the first measurement and should relax as much as possible.

Cuff Measurement:

- The participant's arm circumference should be measured during screening to ensure the appropriate size cuff is used and to exclude morbidly obese participants where the cuff size is too small for their arm. The appropriate cuff should be chosen based on the measurement ranges specified for each cuff. If an arm measurement falls on a number that is specified for two cuffs, both cuffs should be placed on the arm sequentially and the cuff for which the **INDEX ↑**arrow that is marked on the cuff falls within the range bar should be chosen.
- If upper arm circumference is >50 cm (20 in) the participant will be thanked and excluded from the study.

Cuff Placement:

- Do not allow a sleeve to form a tourniquet on the arm.
- Palpate the brachial artery in the antecubital fossa and place the **ART ↓**that is marked on the midline of the bladder of the cuff so that it is over the arterial pulsation of the participant's bare upper arm.

- The lower end of the cuff should be ½ to 1 inch above the inner side of the elbow joint.
- The middle of the cuff should be at the level of the right atrium (the mid-point of the sternum).
- Place the cuff snugly around the bare upper arm so that you can only insert one finger between the cuff and the arm.

Blood Pressure Measurement:

- Use the Omron HEB-907-XL and record values in the Baseline Data REDCap form (Appendix 5).
- Tell the participant that you will be taking 3-4 blood pressure measurements and that neither of you should talk during the measurements.
    - Take a single sitting BP reading with the MODE set to "SINGLE" and record. Wait at least 60 seconds before taking the next blood pressure.
    - Repeat this two more times.
    - The average of the 2nd and 3rd readings will be used as the research BP for this visit.
    - If the 2nd and 3rd BP values are more than 4 mmHg apart, a 4th value will be obtained and the two nearest values will be averaged. This will serve as the research BP for that visit.

IF YOU GET AN ERROR MESSAGE AT ANY POINT, START THE SEQUENCE OVER.

4.3.3 Blood Pressure Medications

Research interns will record all BP medications (and dosage) that the participants are currently taking at the baseline appointment in the REDCap BP Medication Form (Appendix 6). This REDCap form is linked to the Master Drug Data Base Clinical Drugs BioPortal Ontology Service so that when a research intern begins typing a medication name, an appropriate spelling of the drug and all of the available dosages will automatically populate. This will substantially reduce data entry mistakes. If a participant is taking more than one BP medication, the REDcap form will allow them to create multiple entries. The research interns will use the updated Drug Codes for Antihypertensive Agents form used in the CAPTION trial to help them determine which of the patient's medications are appropriate to record (Appendix 7).

4.3.4 Enrollment in WyBP

Before leaving the baseline appointment, the participants will need to be enrolled in WyBP so that they can send home-BP measurements via text message.

- Go to https://vinci.cs.uiowa.edu/meditext2/home/
- Log in with your username and password.
- Select the PharmText BP study from the dropdown menu.
- Click the green Enroll Patient button in the top right corner.
- Enter the participant's phone number starting with the area code, click Next.

- Enter the participant's Record ID from REDCap in the Subject identifier field.
- Leave the email field blank.
- Choose the participant's preferred language (English or Spanish), click Submit.
- You will be taken to an Edit Patient screen that shows the phone number you just registered along with a note at the top saying that the patient was successfully created in the study. Click the green Update button to be taken to the next step.
- Back at the Home Screen, you will see that the Study Summary now shows an additional enrollment and progress made toward the overall enrollment goal. Click the Patients button to assign text message subscriptions to the participant you just enrolled.
- Click on the Patient for whom you need to assign a text message subscription.
- Click the green Add Subscription button in the top right corner.
- Choose the PharmText Baseline Protocol. Set the Start Date to be tomorrow's date. Set the End Date to be 15 days from tomorrow. Set the frequency to 1. Choose the appropriate morning and evening Send Times for the participant to receive the text messages (NOTE: the morning Send Time should be a time after the patient will wake up, but before they take any morning medications. The evening Send Time should be a time that is convenient for the participant between dinner and going to bed.). Make sure both the Send End Message and Send End Email to Managers are checked. Click the green Submit button.

A second set of subscriptions will need to be created for all intervention participants so that they can send their 3 days of BPs each month. These subscriptions will be created by our software developer (unblinded). He will check REDCap once per week to see which new participants have been randomized to the intervention group. Then, he will create subscriptions for them to send 3 days of BPs each month beginning on the date that the participant was enrolled (i.e., if a participant was enrolled on August 15, they will submit their first day of BPs on the 15th, 16th, and 17th of each month throughout follow up). This strategy will allow the pharmacists to see a variety of BPs from different days of the week. The software developer will create the subscriptions using these steps:

- Create subscriptions 2-12 for the participant for the 3 days of text messages each month throughout the 12 months of follow up.
- Click the Patients button to assign a subscription to the appropriate participant.
- Click on the Patient for whom you need to assign a text message subscription.
- Click the green Add Subscription button in the top right corner.
- Choose the PharmText Ongoing Protocol. Set the Start Date to be today's date next month (i.e., if the participant enrolled on April 15th, you would set this Start Date to be May 15th). Set the End Date to be 2 days later. Set the frequency to 1. Choose the same morning and evening Send Times as the previous subscription. Do not check the Send End Message and Send End Email to Managers options until you are creating the final subscription.

4.3.5 Compensation

Once a participant has completed the baseline appointment, a research intern will submit a form for a $50 compensation check to be mailed to the participant's home using the university's online eVoucher system. They will log this submission using the REDCap Compensation Form (Appendix 8).

4.4 Randomization and Treatment Arms

Dr. Emine Bayman created the stratified randomization lists for each clinic site. These lists are being uploaded to a website created by our software developer (unblinded). As participants have completed their home BP measurements, the research pharmacists will log into this website using a unique username and password. They will input the Record ID for the participant they need to randomize as well as the clinic location from which the participant enrolled. The website will inform the pharmacist of group assignment and they will record that in the Group Assignment REDCap form (Appendix 9). The website will store a log with a date and time stamp of which pharmacist randomized each participant to ensure that pharmacists do not intentionally or unintentionally alter the randomization in any way. This strategy should ensure that a relatively equal number of intervention and control participants are enrolled at each clinic.

4.4.1 Control Group:

Once the research pharmacist is informed of the participant's group assignment, they will contact the participants. The pharmacist will discuss their home BP measurements and only provide general education on hypertension. If the BP values remain elevated on home monitoring, the pharmacist will advise the participant to make an appointment with their physician to address BP elevations. This will be the only pharmacist contact for the control group.

4.4.2 Intervention Group:

The pharmacists will have access to the participants' electronic medical records, all information collected by the research interns, and the home BP values that are submitted via text message. Pharmacists will employ a patient-centered approach to improve participant's BP by providing support, education, and recommendations for treatment intensification, as necessary. They will communicate with participants via phone, text message, or email, based on participant preferences. They will not follow a specific protocol, but will base treatment decisions on current BP guidelines. They may schedule more home BP measurements than the 3 days per month. Recommendations to physicians will primarily be made through the electronic medical record to quickly improve BP control. They will also recommend laboratory testing if indicated (e.g., serum potassium or creatinine).

The pharmacists will review the home BP values with the intervention subjects. If the home BP values are controlled, the pharmacist will continue to monitor home BP values.

However, if the pharmacist identifies issues such as poor medication adherence, inability to afford medications or other issues, they will work with the patient and physician to optimize therapy and/or reduce cost. If the pharmacist suspects white coat hypertension, they will make a recommendation to the physician to refer the patient to the University of Iowa ambulatory blood pressure service.

If BP values are elevated, the pharmacist will assess medication adherence, ability to pay for medications and whether the regimen is optimal to control BP based on patient demographics and co-existing conditions. The pharmacist will communicate recommendations for lifestyle and other changes directly to the subject. If medication changes are needed, the pharmacist will communicate to the physician through the electronic medical record. The pharmacist may recommend:

1. Increased dose of a medication.
2. Addition of a medication.
3. Discontinuation of a medication.
4. Modification of the regimen to optimize therapy, improve convenience (e.g. fixed-dose combinations) or reduce cost.

All participants in the pharmacist intervention group will continue to have access to a research pharmacist for the entire 12 months of follow up. Additionally, they will be asked to continue measuring and texting BP values (1 morning, 1 evening) for 3 days each month throughout the 12-month follow up.

The pharmacists will typically contact with the participants every 2 weeks while BP is not controlled. Once BP is controlled, they will continue monitoring the participant's records and home BPs and make contact at least every 2 months to support adherence and reassess BP control.

The REDCap forms that the pharmacists will use to record data are shown in Appendix 10

4.5 6-Month Visit Procedures

All participants will be asked to return to the clinic where they enrolled at for a 6-Month appointment with a research intern. To allow for flexibility with scheduling, 6-Month appointments will be allowed to occur anytime between 5 Months and 7 Months after the enrollment date. This BP value will be the outcome BP value. If a participant is not able to make it to the clinic during this window, but does want to come in after the 7 Month date, this will be allowed and all data will be collected, however, it will not be counted in the 6-month outcome and the 6-month outcome will be considered missing. In this case, a note will be placed in the participant's record and these data may not be used in analyses.

At the 6-Month appointment, the research intern will collect the research BP values, any BP medications that the participants are currently taking, the last 3 BP values that were

recorded by the participant's home BP cuff, and test the home BP cuff for accuracy. If the home BP cuff appears to be measuring inaccurately, it will be replaced. The participant will be sent another $50 compensation check. All of the procedures outlined at baseline will be followed again, but the data will be collected on separate 6 Month REDCap forms (not shown).

4.6 12-Month Visit Procedures

All participants will be asked to return to the clinic for a 12-Month appointment with a research intern. To allow for flexibility with scheduling, 12 Month appointments will be allowed to occur anytime between 11 Months and 13 Months after the enrollment date. If a participant is not able to make it to the clinic during this window, these data will be missing.

At the 12-Month appointment, the research intern will collect the research BP values, any BP medications that the participants are currently taking, a 12-Month Exit Survey (Appendix 11) asking for the participant's feedback about the study, and send another $50 compensation check. All of the procedures outlined at baseline will be followed again, but the data will be collected on separate 12-Month REDCap forms (not shown). Participants will also be asked about any hospitalizations or emergency room visits that occurred over the 12-month follow up period, especially those that occurred outside of the University of Iowa system (Appendix 12).

Additionally, the research team will conduct a 12-Month Medical Record Review for each participant. This chart review will occur separately from the 12-Month visit and will not require any effort on the part of the participant. A member of the research team will screen the participant's medical record for all clinic/quick care visits (documenting reason), any emergency room visits (documenting reason), and any hospitalizations (documenting reason and length of stay). These data will be recorded on the REDCap forms in Appendix 13. Again, multiple entries will be allowed by REDCap.

4.7 Adverse Event Reporting and Determination

As this is a low-risk study, we do not anticipate many adverse events. However, if any member of the research team becomes aware of a potential adverse event, they will report it to Dr. Peter Snyder (peter-snyder@uiowa.edu). He will review the event and make a ruling as to whether the adverse event is related to the study or not. If he determines that an adverse event has occurred, the DSMB and IRB will be notified as quickly as possible. Until an official ruling has been made by Dr. Peter Snyder, other members of the research team should not be notified, because they are blinded to group assignment.

4.8 Unanticipated Problem Reporting

There are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or

economic harm instead of physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased risk of harm, but no harm occurs. If an unanticipated problem occurs that does not involve an adverse event, it will still be reported to the DSMB and the IRB under HHS regulation 45 CFR Part 46 (Unanticipated Events HHS Policy).

5. Study Outcomes

The study will have one primary outcome and three secondary outcome measures for the three specific aims. The primary outcome is change in SBP 12 months after the start of the intervention. The secondary outcomes are change in DBP 12 months after the start of the intervention, the number of medication changes as a measure of treatment intensification, and the additional cost of the intervention.

Aim 1: Determine if our intervention leads to decreases in SBP.

Our working hypothesis is that there will be greater decreases in both SBP and DBP among the pharmacist-intervention group than among controls. We will compute the change in SBP for each subject at 12 months compared to their initial SBP. The SBP readings will be collected at enrollment and at 12-months by research assistants. The primary outcome measure for Aim 1 will be the difference in mean SBP between the control and intervention groups at 12 months.

Aim 2: Determine if our intervention leads to intensification of therapy.

Our working hypothesis is that there will be a greater number of medication changes in the intervention group compared to the control group. We will count the number of medication changes (dose increased, dose decreased, drug stopped, drug started) during the 12 months following the start of the intervention. The total number of medication changes will be the primary outcome measure for Aim 2. In addition, we will determine the number of pharmacist recommendations that were accepted by physicians. These are process measures: we found in our previous studies that BP improvement was primarily related to medication changes. We are assuming that changes are a sign of close monitoring. Indeed, we have used this measure previously. However, we realize that not all medication changes are equal, and thus we will record both medication trends and final treatment for each patient.

Aim 3: Determine the cost effectiveness of the intervention.

Our working hypothesis is that our intervention will be cost effective when compared to the control group. In addition, we will compare these results to previous pharmacist interventions. Because much pharmacist time is spent on non-direct patient care activities, we are convinced that our bi-directional texting approach will be both labor and cost saving. We will compute the incremental cost effectiveness ratio (ICER) using the total costs of doctor visits, pharmacist time, medications and medication changes during the 12 months of the trial. The ICER will be the difference between the control and intervention groups in average total cost

divided by the difference in average decrease of SBP and DBP. The ICER will be expressed in the dollars per mmHg reduction in BP and will be the primary outcome in this Aim.

6. Statistical Design and Power

Aim 1 Analysis: The analysis will be done on an intent-to-treat basis regardless of the number of reported BP readings or the number of pharmacist interactions with the participant. Our primary outcome will be a comparison of mean SBP values at 12 months. We will use linear mixed effects models (LMMs) with BP as the outcome. We will explore the timing of the change by also evaluating BP at 6 months. To test the intervention, we will include time (baseline, 6 month, 12 month) as a fixed effect factor and its interaction with treatment arm. We will use random effects for clinic and physician nested within clinic to account for practice heterogeneity between clinics and providers. Temporal correlation will be accounted for by using an autoregressive error structure. Specifically, the model will be given as

$$BP_{cpit} = \tau_t + \alpha_c + \gamma_{cp} + (\omega_t + \nu_{tc} + \xi_{tcp})X_{cpi} + \epsilon_{cpit},$$

$$c = 1, \dots, C, \qquad p = 1, \dots, P_c, \qquad i = 1, \dots, n_{cp}, \qquad t \in \{0,6,12\},$$

$$(\alpha_c, \gamma_{cp})' \overset{\text{iid}}{\sim} N(0, G_1),$$

$$(\nu_{0c}, \nu_{6c}, \nu_{12c})' \overset{\text{iid}}{\sim} N(0, G_2),$$

$$(\xi_{0cp}, \xi_{6cp}, \xi_{12cp})' \overset{\text{iid}}{\sim} N(0, G_3),$$

$$(\epsilon_{cpi0}, \epsilon_{cpi6}, \epsilon_{cpi12})' \overset{\text{iid}}{\sim} N(0, R),$$

where C is the number of clinics, P_c is the number of providers within the c^{th}clinic, n_{cp} is the number of subjects recruited under the p^{th} provider in the c^{th} clinic, $BP_{(cpit)}$ is the blood pressure at time t for the i^{th} subject under the p^{th} provider within clinic c, τ_t is the control mean at time t, α_c and γ_{cp} are the random control effects for the clinic and provider-nested-within-clinic respectively, ω_t is the treatment effect at time t, ν_{tc} and ξ_{tcp} are the random treatment effects for the clinic and provider-nested-within-clinic respectively, X_{cpi} equals 1 if the i^{th} subject under the p^{th} provider within clinic c is assigned to the treatment group and zero otherwise, ϵ_{cpit} is the (auto-correlated) noise term, and G_1, G_2, G_3, and R are covariance matrices for the random effects. This model will also be estimated for DBP.

Second, transition to control for patients who were uncontrolled at their baseline visit will be modeled using a generalized linear mixed effects model (GLMM) based on the Bernoulli distribution with a logistic link. We will test the intervention by including a fixed-effects term for the treatment assignment (intervention versus control). As before, we will include random effects for provider nested within clinic. Specifically, the model will be

$$\text{logit}\left(\mathbb{P}(Z_{cpi6} = 1 | Z_{cpi0} = 0)\right) = \tau + \alpha_c + \gamma_{cp} + (\omega + \nu_c + \xi_{cp})X_{cpi},$$

$$(\alpha_c, \gamma_{cp})' \overset{\text{iid}}{\sim} N(0, G_1),$$

$$(\nu_c, \xi_{cp})' \overset{\text{iid}}{\sim} N(0, G_2),$$

where Z_{it} equals 1 if the i^{th} subject under the p^{th} provider within clinic c is controlled at time t, $t \in \{0,6\}$, and zero otherwise.

Third, we will assess the duration of the change by modeling the odds of having controlled BP at 12 months among those uncontrolled at baseline but controlled at 6 months using a GLMM similar to that described above. All three models will contain any covariates (e.g., age, sex) that were not sufficiently addressed through randomization. In all analyses, the random effects incorporated into the final model will be chosen via Akaike Information Criterion with correction for small sample sizes (AICc).

Power: Based on prior work with the CAPTION trial, we expect a mean decrease in SBP of 17.3 (SD = 17.7) mmHg in the intervention arm and a decrease of 11.6 (SD = 18.2) mmHg in the control arm. We expect a difference of 5.65 mmHg between the groups with an expected pooled standard deviation of 17.9 with equal sized groups. In order to have 90% power to detect a difference of 5.7 mmHg or larger decrease in SBP with a Type I error rate of 5% and a standard deviation of 17.9 mmHg, we would need 180 subjects per arm or 360 subjects total.

In preliminary work in the CAPTION trial, 13.4% of control subjects dropped out or were lost to follow-up. 14.0% of subjects dropped out of the intervention arm during the first 9 months. In order to retain power after reasonable attrition rates over 12 months, we will recruit an additional 14% in each group to ensure we have at least 85% power. In addition, the sample size should be slightly increased to accommodate the interim analyses. This increases our total sample size to 420.

One interim analysis is planned after outcome data are received and the results are reported to the Data Safety and Monitoring Board from the first half of the study. The interim monitoring method of Lan and DeMets will be used with O'Brien-Fleming alpha spending function for the interim analyses. Accordingly, type I error rate of 0.00305 for the interim analysis and 0.4695 will be used for the final analyses. The current sample size of 420 patients total accommodates the interim analyses.

Aim 2 Analysis: The analysis will be done on an intent-to-treat basis regardless of the number of reported BPs or the number of pharmacist interactions with the subject. Our primary outcome will be the number of medication changes over 12 months in the control and intervention groups. We will use a GLMM based on the Poisson distribution with a log link function, and as in Aim 1 we will incorporate random effects for clinic and physician nested within clinic to account for practice heterogeneity between clinics and providers. As the observed treatment effects in those clusters are likely to be non-independent, we will include both random intercepts and random treatment effect for the intervention factor. Specifically, the model will be given as

$$\log\left(\mathbb{E}\left(Y_{cpi}\right)\right) = \tau + \alpha_c + \gamma_{cp} + \left(\omega + \nu_c + \xi_{cp}\right)X_{cpi},$$
$$\left(\alpha_c, \gamma_{cp}\right)' \overset{\text{iid}}{\sim} N(0, G_1),$$
$$\left(\nu_c, \xi_{cp}\right)' \overset{\text{iid}}{\sim} N(0, G_2),$$

where Y_{cpi} is the number of medication changes for the i^{th} subject under the p^{th} provider within clinic c. The random effects incorporated into the final model will be chosen via AICc.

Power: Based on existing work, we expect an average of 4.9 medication changes in the intervention group (SD = 5.1) and an average of 1.1 medication changes in the control group (SD = 1.6). We would expect a difference of 3.8 changes per year with a pooled standard deviation of 3.8. In order to have 85% power to detect a difference of 3.8 or more changes with a Type I error rate of 5% and a standard deviation of 3.8, we would need 19 subjects per arm or 38 total. Considering both 14% loss to follow-up and adjusting the type I error rate for interim analysis, power of the study with our sample size of 420 will be more than adequate.

Aim 3 Analysis: The analysis will be performed on an intent-to-treat basis regardless of the number of reported BP measurements or the number of pharmacist interactions with the subject. The perspective of this cost analysis is society in general. For each patient encounter, pharmacists will record the number of minutes spent in the following activities: medical record review, consultation, patient assessment, ordering medications, medical education, lifestyle education, BP measurement education, making recommendations, and documentation in the medical record. Pharmacist costs will be estimated by multiplying the time spent by their compensation rate. Costs for clinic visits will be obtained from the university. Utilization measures will be converted to costs per subject using the Medicare fee schedule for visits. Pharmacist and physician salaries will be obtained from the Bureau of Labor Statistics. The average wholesale drug cost for prescription medications will be obtained from Lexicomp Online (https://online.lexi.com). Generic prices will be used when available. The drug cost per prescription for each subject will be calculated by multiplying the average wholesale price (AWP) by frequency and dose.

We assume that subjects in the intervention and control groups will have similar characteristics. However, if there are significant differences between the subjects in these groups, costs will be predicted using a multivariate generalized linear model with a gamma family and a log link to control for these differences.

We will determine the cost of the intervention by subtracting the average total cost (pharmacist, clinic, and drugs) for the intervention group from the average total costs for the control group. The ICER is calculated as the cost differential from the intervention divided by the outcome differential from the intervention. Our primary outcome will be average decrease in SBP, and the outcome differential will be the average decrease in SBP for the control group minus the average decrease in SBP for the intervention group. The result of this analysis will be an ICER, which gives the additional cost of the intervention per mm Hg of SBP decrease.

We will conduct at least two sensitivity analyses. Because the drug costs (average wholesale prices) from Lexicomp often overstate the actual prices paid by insurance companies and patients, we will adjust our drug costs and re-estimate our cost-effectiveness analysis. Specifically, the Kaiser Family Foundation estimates that average wholesale prices are, on average 17% higher than weighted acquisition costs for brand-name drugs, and 80% higher for generic drugs. In addition, pharmacist time can be represented by either wages per hour, or the

amount that pharmacists can bill Medicare for each activity. We will consider both ways to measure the value of pharmacists' time.

7. Data Safety and Monitoring

All procedures and protocols will be developed by the PIs and the study coordinator with protection of the participants and data as the highest priority. All procedures will be reviewed by the University of Iowa IRB as well as the Data and Safety Monitoring Board prior to being implemented (additional information about DSMB members and responsibilities can be found in the DSMB Charter). The study coordinator will thoroughly train and monitor all research interns during the course of the study and will be available to answer questions via phone when not in the clinic.

8. Study Responsibilities

By signing this protocol, the study's two PIs agree to be responsible for implementing and maintaining quality control and quality assurance systems to ensure that all work incidental to this protocol is conducted and data are generated, documented, and reported in compliance with the protocol, with accepted standards of Good Clinical Practice (GCP), and with all applicable federal, state, and local laws, rules, and regulations relating to the conduct of the clinical study.

Once the study activities are completed, the PIs will be primarily responsible for creation, review, and submission of publications and presentations relating to major aspects of the study and approved analyses within a timely fashion.

The manuscript containing the overall study results will be distributed to all study investigators at the University of Iowa for review and comment before submission to a peer-reviewed journal with a reasonable period for review, but the final content will be at the discretion of the PIs. Any other manuscripts containing these data, including abstracts, will be distributed to all relevant study investigators who are participating on such publications before submission, with a reasonable period for review. Submitted publications will conform to international standards for biomedical manuscripts, including those regarding authorship.

9. Ethical Considerations

By signing this protocol, the PI agrees to conduct the study in compliance with the protocol; the Declaration of Helsinki; and all applicable federal, state, and local laws, rules, and regulations relating to the conduct of the clinical study.

The University of Iowa has overall responsibility for the conduct of the study, including assurance that the study meets the sponsor's regulatory requirements.

The PIs have both ethical and legal responsibility to ensure that each subject being considered for inclusion in this study is given a full explanation of the study. Informed consent will be obtained from all subjects before any data are collected and before any study-related procedures are performed. Before and after subject provision of informed

consent, research team members will be available via email or phone to answer questions or concerns regarding procedures and risks.

Subject confidentiality will be maintained throughout the clinical study. Subject information collected in this study will comply with the standards for protection of privacy of individually identifiable health information as promulgated by HIPAA and as mandated in Title 45 CFR Parts 160 and 164. All records will be kept confidential, and the subject's name will not be released to non-authorized persons or entities at any time. Subject records will not be released to anyone other than members of the research team at each site who have a need for such information, and responsible regulatory authorities when requested. In all cases, caution will be exercised to assure the data are treated confidentially and that the subject's privacy is guaranteed.

Hard copy records containing subject data collected at sites (informed consent documents) will be stored in a locked cabinet in a locked office. Identification numbers will be used in place of names on report forms. All electronic study data will be stored on encrypted, password-protected servers located within security firewalls, such that only members of the research team who need access will be allowed access to study files. Subject data will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which disclosure of the requested data would be permitted by the HIPAA Privacy Rule. If needed, any transport of electronic data will occur via a password-protected disk or secure transfer protocol.

All subjects will consent, through their IRB-approved informed consent document to release of protected health information to the University of Iowa research teams as part of the consent process.

Appendix 1: Participating Sites

Clinic Name and Location	Lead Physician Name	Population in 2010 Census	Minority/ Rural Population
UI River Crossing Riverside, Iowa	David Bedell, MD	2,800 in surrounding communities	70% Hispanic 0.8% Black 43.8% Rural
Scott Blvd Iowa City, Iowa	Katherine Imborek, MD	3,736 in West Liberty, Iowa	52.2% Hispanic 0.4% Black 12.5% Rural
UIHC Iowa City, Iowa	Daniel Fick, MD	67,862	5.3% Hispanic 5.8% Black 18.7% Rural
IRL Coralville, Iowa	Daniel Fick, MD		
North Liberty North Liberty, Iowa	Daniel Fick, MD		
Muscatine Muscatine, Iowa	Michael Maharry, MD	22,886	16.6% Hispanic 2.3% Black 23.7% Rural

Appendix 2: Study Procedures Timeline

Time	Activity	Control Group	Intervention Group
Day 0	Screening Consent Baseline Appointment	X	X
Day 1 – Days 7-15	Home BP measured and returned via text message	X	X
Days 7-15 – Day 18	Participants randomized; Pharmacists review home BP values, contact participants	X	X
Day 18 – 6 Months	Participants text home BP values 3 days per month Pharmacists monitor BP, adjust treatment as needed		X
6 Months	Participants return to clinic for appointment	X	X
6 Months – 12 Months	Participants text home BP values 3 days per month Pharmacists monitor BP, adjust treatment as needed		X
12 Months	Participants return to clinic for appointment	X	X

Appendix 3: REDCap Screening Form

Screening

Record ID

_____

Screening Information

Clinic

- ◯ UIHC
- ◯ IRL
- ◯ North Liberty
- ◯ Scott Blvd (IC)
- ◯ River Crossing (Riverside)
- ◯ Muscatine (Muscatine)

Date

_____

Screening Intern

- ◯ Brady Letney
- ◯ Trey Krupp
- ◯ Michael Bielecki
- ◯ Miguel Gutierrez
- ◯ Alec Hanson
- ◯ Shelby Francis

Patient Information from Epic (double check with patient)

Patient First Name

_____

Patient Last Name

_____

MRN

_____

Age

_____

(Patient must be 21 - 100 to be eligible.)

Patient Zip Code

_____

Patient RUCA Code

_____

(RUCA code must be >=4 to be eligible.)

Blood Pressure Information

At least 2 elevated BP measurements in past 18 months? Elevated BP is: >= 145 mmHg SBP or >= 95 mmHg DPB. Elevated BP values taken today do count!	◯ Yes ◯ No (Patient must have at least 2 elevated BP measurements within past 18 months, at least 2 weeks apart from each other, to be eligible.)
First Elevated SBP	_____
First Elevated DBP	_____
Date of First Elevated BP	_____
Second Elevated SBP	_____
Second Elevated DBP	_____
Date of Second Elevated BP	_____

Information from Patient

Is female patient currently pregnant, or planning to become pregnant in next 12 months?	◯ Yes ◯ No ◯ Patient is male (Patients currently or planning to become pregnant are NOT eligible.)
Prisoner Status	◯ Yes ◯ No (Patients with prisoner status are NOT eligible.)
Does the patient have a condition that prevents them from providing their own written informed consent?	◯ Yes ◯ No (Patients who cannot provide their own consent are NOT eligible.)
Arm circumference (cm)	_____ (Patients with arm circumference greater than 50 cm (20 in) are NOT eligible.)
Preferred Language	◯ English ◯ Spanish

Patient Eligibility

Is Patient Eligible?	◯ Yes ◯ No

Appendix 4: Consent Forms

INFORMED CONSENT DOCUMENT

Project Title: A Pharmacist Intervention for Monitoring and Treating Hypertension Using Bidirectional Texting.

Principal Investigator: Linnea Polgreen, PhD

Research Team Contact: Shelby Francis 319-678-8037

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult between the ages of 21 and 100 years, have had at least 2 blood pressure measurements of ≥145 mmHg systolic or ≥95 mmHg diastolic in the past 18 months, live in a rural area, and do not have an upper arm circumference greater than 50 cm (20 in).

The purpose of this research study is to determine whether our text messaging approach combined with a pharmacist-based intervention improves blood pressure management in a cost-effective manner.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 800 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 12 months. The initial appointment will last approximately 30 minutes. You will return to the clinic for appointments at 6 and 12 months. These appointments are expected to last for approximately 30 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

A member of the research team will take your blood pressure up to 4 times during the baseline appointment and will also collect additional data (age, sex, race, rural residence, ethnicity and language, marital status, insurance, body mass index, other conditions, blood pressure medications, smoking and vaping status, current alcohol intake, and distance from your home to the clinic) from you and your medical record. They will also ask you to provide the name and phone number for a friend or family member who will know how to reach you during the 12 months of follow up should the research team

You will be given a blood pressure cuff and will be asked to measure your blood pressure for the next 7-15 days, in the morning and in the evening. We will text you at the times you choose, and you will respond with your blood pressure measurements. As soon as we receive 14 measurements, the text messages will stop. A cell phone will be provided for you if you do not already have one. Instructions on proper blood pressure measurement and how to text the values to the research team will be provided.

After the baseline appointment, you will be randomized to the control group (text messaging only) or intervention group (text messaging plus pharmacist). This means that whichever study assignment you receive will be determined purely by chance, like flipping a coin. You will have an equal chance of receiving either one of the two study assignments.You will be contacted by a research pharmacist informing you about your group assignment. If you are assigned the texting-only group, the pharmacist will discuss you blood pressure measurements with you and give you information about blood pressure control.

If you are assigned to the text-message-plus-pharmacist group, you will be asked to text your blood pressure measurements 3 days per month for the remaining 12 months. The pharmacist will ask you how you would like to be contacted – phone, email or text. They will have access to your medical record and will ask you about your blood pressure, diet, medications, etc. The pharmacist will monitor your blood pressure for 12 months and will encourage you to take your medications. The pharmacist will work with your physician and recommend changes to your medications if needed.

The research assistant will call to schedule an appointment for you to return to the clinic 6 months after your baseline visit. During this visit, we will measure your blood pressure up to 4 times and double-check your blood pressure medications. We ask that you bring the blood pressure monitor to this appointment so that we can make sure that it is still working properly and also check the blood pressure values that have been saved on the device.

The research assistant will call to schedule an appointment for you to return to the clinic at the end of the study (12 months). During this visit, we will measure your blood pressure up to 4 times and double-check your blood pressure medications. We will ask you about any hospitalizations or emergency room visits that have occurred during the study, particularly those that occurred outside of the University of Iowa system. We will collect clinic/Quick Care visits, emergency rooms visits, and any hospitalizations you have had over the past 12 months within the University of Iowa system from your medical record. We will also ask you to complete an exit survey asking for your opinions about the study and any interactions with the pharmacists.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding high blood pressure, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that

your data might be used to develop products or tests that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. There are no plans to provide financial compensation to you should this occur.

Your data will be stored *with a code which may be linked to* your blood pressure measurements and data collected from your medical record. This code will be linked to your name so that we can identify which data are yours. If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Linnea Polgreen, 319-384-4091. However, if some research with your data has already been completed, the information from that research may still be used.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored for future research.

_____ Yes _____ No

WHAT ARE THE RISKS OF THIS STUDY?

The main foreseeable risk of this study is loss of confidentiality. Text messages are not encrypted, and it is possible that your blood pressure measurements could be seen by others. In addition, if your blood pressure is elevated, medications may be recommended, and these medications may have side effects. There may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study if you are in the control group. We don't know if you will benefit if you are in the intervention group. However, we hope that, in the future, other people might benefit from this study because of the knowledge gained in monitoring blood pressure.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could discuss high-blood-pressure treatment with your physician and receive the same treatments that the pharmacists in the study recommend.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your address so a check can be mailed to you. You will be paid $50 for participation, $50 for attending the 6-month visit and $50 for

attending the 12-month visit($150 total for all 3 appointments). .

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store all of the data we collect from you on a secure server that can only be accessed by the research team. Paper forms will be kept in a locked cabinet in a locked office. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not

FOR IRB USE ONLY
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$STAMP_EXP_DT

research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Linnea Polgreen, College of Pharmacy, 1801 S. Grand Ave. #340, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to contact the research team at 319-775-0689.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Shelby Francis (319-678-8037, Shelby-francis@uiowa.edu). If you experience a research-related injury, please contact: Linnea Polgreen (319-384-4091).

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

FOR IRB USE ONLY
$STAMP_IRB
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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del Proyecto: Una intervención de farmacéutico para la supervisión y tratamiento de la hipertensión usando mensajes de texto bidireccional.

Investigator Principal: Linnea Polgreen

Contacto del equipo de investigación: Shelby Francis 319-678-8037

Este formulario de consentimiento describe el estudio de investigación para ayudarle decidir si quiere participar. Este formulario proporciona información importante sobre lo que se le pedirá durante el estudio, sobre los riesgos y beneficios del estudio, y sobre sus derechos como sujeto de investigación.

- Si tiene preguntas, o si no entiende algo de este formulario, debe de preguntarle al equipo de investigación por más información.
- Usted debería discutir su participación con cualquier persona que elija, como la familia o los amigos.
- No este de acuerdo en participar en este estudio a menos de que el equipo de investigación haya contestado sus preguntas y decida qué quiere ser parte de este estudio.

¿QUE ES EL OBJETIVO DE ESTE ESTUDIO?

Este es un estudio de investigación. Le invitamos a participar en este estudio de investigación porque eres un adulto de una edad elegible y has tenido por lo menos 2 medidas de presión arterial mas de 145 mmHg sistólica y/o mas de 95 mmHg diastólica y vives en una zona rural.

El objetivo de este estudio es para determinar si nuestros mensajes de texto combinado con una intervención de farmacéutico mejora la administración de la presión arterial en una manera costo-efectiva.

¿CUANTAS PERSONAS PARTICIPARAN?

Aproximadamente 800 personas tomaran parte en este estudio realizado por investigadores en la Universidad de Iowa.

¿CUANTO TIEMPO ESTARE EN ESTE ESTUDIO?

Si usted acepta tomar parte en este estudio, su participación tendrá una duración de 12 meses. La cita inicial durará 20 minutos. Regresará a la clínica para citas en mes 6 y en mes 12. Se espera que estas citas duren aproximadamente 30 minutos.

¿QUE PASARA DURANTE ESTE ESTUDIO?

Un miembro del grupo de investigación tomará su tensión arterial 3 veces durante la cita de referencia y también coleccionará datos adicionales (edad, sexo, raza, residencia rural, pertenencia étnica y lengua, estado civil, seguro, índice de masa de corporal, enfermedades crónicas, medicamentos, cualquier efecto secundario de medicamentos, y distancia de su casa a la clínica) de su registro médico. después de la cita de referencia, se le asignará al azar al grupo de control (solo mensajes de texto) o al grupo de intervención (mensajes de texto más farmacéutico). Esto significa que cualquier asignación de estudio que recibas se determinará puramente por casualidad, cómo lanzar una moneda. Tendrá la misma posibilidad de recibir una de las dos asignaciones de estudio.

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FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del Proyecto: Una intervención de farmacéutico para la supervisión y tratamiento de la hipertensión usando mensajes de texto bidireccional.

Investigator Principal: Linnea Polgreen

Contacto del equipo de investigación: Shelby Francis 319-678-8037

Este formulario de consentimiento describe el estudio de investigación para ayudarle decidir si quiere participar. Este formulario proporciona información importante sobre lo que se le pedirá durante el estudio, sobre los riesgos y beneficios del estudio, y sobre sus derechos como sujeto de investigación.

- Si tiene preguntas sobre o si no entiende algo de este formulario, debe de preguntarle al equipo de investigación por mas información.
- Usted debería discutir su participación con cualquier persona que elija, como la familia o los amigos.
- No consiente en participar en este estudio a menos que el equipo de investigación haya contestado sus preguntas y decide qué quiere ser parte de este estudio.

WHAT IS THE PURPOSE OF THIS STUDY?

Este es un estudio de investigación. Lo invitamos a participar en este estudio de investigación porque es un adulto entre las edades de 21 y 100 años, ha tenido al menos 2 mediciones de presión arterial de ≥ 145 mmHg sistólica o ≥ 95 mmHg diastólica en los últimos 18 meses, vive en un área rural, y no tiene una circunferencia del brazo superior a 50 cm (20 in).

El objetivo de este estudio es para determinar si nuestros mensajes de texto combinado con una intervención de farmacéutico mejora la administración de la presión arterial en una manera costo-efectiva.

¿CUANTAS PERSONAS PARTICIPARAN?

Aproximadamente 420 personas tomaran parte en este estudio realizado por investigadores en la Universidad de Iowa.

¿CUANTO TIEMPO ESTARE EN ESTE ESTUDIO?

Si usted acepta tomar parte en este estudio, su participación tendrá una duración de 12 meses. La cita inicial durará 30 minutos. Regresará a la clínica para citas en el mes 6 y mes 12. Se espera que estas citas duren aproximadamente 30 minutos.

¿QUE PASARA DURANTE ESTE ESTUDIO?

Un miembro del equipo de investigación tomará su presión arterial hasta 4 veces durante la cita inicial y también recopilará datos adicionales (sexo, raza, etnia, idioma preferido, estado civil, seguro, nivel de educación, índice de masa corporal, afecciones crónicas). , medicamentos para la presión arterial, estado de fumar, consumo actual de alcohol y distancia de su casa a la clínica) de usted y su historial médico. También le pedirán que proporcione el nombre y el número de teléfono de un amigo o familiar que sepa cómo comunicarse con usted durante los 12 meses de seguimiento si el equipo de investigación tiene

problemas para comunicarse con usted. Si contactamos a esta persona, solo le diremos que usted está en un estudio de investigación en la Universidad de Iowa, no de qué trata el estudio.

Le darán un brazalete de presión arterial y se le pedirá que mida su presión arterial durante los próximos 7 a 15 días, por la mañana y por la noche. Le enviaremos un mensaje de texto en los tiempos que usted elige, y usted responderá con sus medidas de presión arterial. Tan pronto como recibamos 14 juegos de medidas, los mensajes de texto pararán. Se proporcionará un teléfono celular para usted si no tienes uno. Instrucciones sobre la medición correcta de la presión arterial y cómo enviar los números al grupo de investigación.

Después de la cita inicial, se lo asignará al azar al grupo de control (solo mensajes de texto) o al grupo de intervención (mensajes de texto más farmacéutico). Un farmacéutico investigador se comunicará con usted para informarle sobre su asignación grupal. Si se le asigna el grupo de solo mensajes de texto, el farmacéutico analizará sus mediciones de presión arterial con usted y le brindará información sobre el control de la presión arterial.

Si se le asigna al grupo de mensaje de texto más farmacéutico, se le pedirá que envíe un mensaje de texto con sus mediciones de presión arterial tres días al mes durante los 12 meses restantes. El farmacéutico le preguntará cómo desea que lo contactemos: teléfono, correo electrónico o mensaje de texto. Tendrán acceso a su registro médico y le preguntarán sobre su presión arterial, dieta, medicamentos, etc. El farmacéutico controlará su presión arterial durante 12 meses y lo alentará a tomar sus medicamentos. El farmacéutico trabajará con su médico y recomendará cambios en sus medicamentos si es necesario.

El asistente de investigación lo llamará para programar una cita para que regrese a la clínica 6 meses después de su visita de referencia. Durante esta visita, mediremos su presión arterial hasta 4 veces y revisaremos sus medicamentos para la presión arterial. Le pedimos que traiga el monitor de presión arterial a esta cita para que podamos asegurarnos de que sigue funcionando correctamente y también verificar los valores de presión arterial que se han guardado en el dispositivo.

El asistente de investigación lo llamará para programar una cita para que regrese a la clínica al final del estudio (12 meses). Durante esta visita, mediremos su presión arterial hasta 4 veces y revisaremos sus medicamentos para la presión arterial. Le preguntaremos sobre cualquier hospitalización o visita a la sala de emergencias que haya ocurrido durante el estudio, particularmente aquellas que ocurrieron fuera del sistema de la Universidad de Iowa. Recolectaremos de su registro médico las visitas a la clínica / atención rápida, las visitas a la sala de emergencias y cualquier hospitalización que haya tenido en los últimos 12 meses dentro del sistema de la Universidad de Iowa. También le pediremos que complete una encuesta de salida solicitando sus opiniones sobre el estudio y cualquier interacción con los farmacéuticos.

ALACENAMIENTO DE DATOS PARA USO FUTURO

Como parte de este estudio, estamos obteniendo datos de usted. Nos gustaría estudiar sus datos en el futuro, una vez que finalice este estudio.

Es posible que las pruebas que podríamos usar para estudiar sus datos ni siquiera existan en este momento. Por lo tanto, solicitamos su permiso para almacenar sus datos para que podamos estudiarlos en el futuro. Estos

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estudios futuros pueden proporcionar información adicional que será útil para comprender la presión arterial alta, pero es poco probable que lo que aprendamos de estos estudios tenga un beneficio directo para usted. Es posible que sus datos se utilicen para desarrollar productos o pruebas que puedan patentarse y licenciarse. No hay planes para proporcionarle una compensación financiera si esto ocurre.

Sus datos se alacenarán con un código que puede estar vinculado a sus mediciones de presión arterial y a los datos recopilados de su registro medico. Este código se vinculará a su nombre para que podamos identificar qué datos son suyos. Si está de acuerdo con el uso futuro de sus datos, pero decide en el futuro que desea que se eliminen de investigaciones futuras, debe comunicarse con Linnea Polgreen, 319-384-4091. Sin embargo, si alguna investigación con sus datos ya se ha completado, la información de ese estudio todavía se puede ser utilizada.

Coloque sus iniciales en el espacio en blanco al lado de Sí o No para cada una de las siguientes preguntas:

Mis datos pueden ser almacenados para futuras investigaciones.

_____SI _____NO

WHAT ARE THE RISKS OF THIS STUDY?

El principal riesgo previsible de este estudio es la pérdida de confidencialidad. Los mensajes de texto no están encriptados, y es posible que otras personas puedan ver sus mediciones de presión arterial. Además, si su presión arterial está elevada, se pueden recomendar medicamentos, y estos medicamentos pueden tener efectos secundarios. Puede haber otros riesgos desconocidos, o riesgos que no anticipamos, asociados con estar en este estudio.

WHAT ARE THE BENEFITS OF THIS STUDY?

No sabemos si se beneficiará. Sin embargo, esperamos que, en el futuro, otras personas puedan beneficiarse de este estudio debido al conocimiento adquirido en el monitoreo de la presión arterial.

¿QUÉ OTRAS OPCIONES DE TRATAMIENTO HAY?

Antes de decidir si desea participar o no en este estudio, su médico discutirá las otras opciones que están disponibles para usted. En lugar de participar en este estudio, podría hablar sobre el tratamiento de la presión arterial alta con su médico y recibir los mismos tratamientos que recomiendan los farmacéuticos del estudio.

¿ME COSTARÁ ALGO ESTAR EN ESTE ESTUDIO?

No tendrá ningún costo por participar en este estudio de investigación. Usted y / o su compañía de seguro médico / hospitalario seguirán siendo responsables de sus gastos médicos regulares.

¿ME PAGARÁN POR PARTICIPAR?

Si, le pagarán por participar en este estudio de investigación. Deberá proporcionar su dirección para que se le pueda enviar un cheque por correo. Le pagarán $50 por participación, $50 por asistir a la visita de 6 meses y $50 por asistir a la visita de 12 meses y devolver el monitor de presión arterial.

¿QUIÉN ESTÁ FINANCIANDO ESTE ESTUDIO?

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Los Institutos Nacionales de la Salud (NIH) financian este estudio de investigación. Esto significa que la Universidad de Iowa está recibiendo pagos de los NIH para apoyar las actividades que se requiren para realizar el estudio. Nadie en el equipo de investigación recibirá un pago directo o un aumento en el salario de los NIH para realizar este estudio.

¿QUÉ PASA CON LA CONFIDENCIALIDAD?

Mantendremos su participación en este estudio de investigación confidencial en la medida en que lo permita la ley. Sin embargo, es posible que otras personas, como las que se indican a continuación, tomen conciencia de su participación en este estudio y puedan inspeccionar y copiar los registros relacionados con esta investigación. Algunos de estos registros podrían contener información que lo identifique personalmente.

- agencias reguladoras del gobierno federal,
- departamentos de auditoría de la Universidad de Iowa, y
- la Junta de Revisión Institucional de la Universidad de Iowa (un comité que revisa y aprueba los estudios de investigación)

Para ayudar a proteger su confidencialidad, almacenaremos todos los datos que recopilamos de usted en un servidor seguro al que solo puede acceder el equipo de investigación. Los formularios en papel se guardarán en un armario cerrado con llave en una oficina cerrada con llave. Si escribimos un informe o artículo sobre este estudio o compartimos el conjunto de datos del estudio con otros, lo haremos de tal manera que no pueda ser identificado directamente.

Los hospitales y clínicas de la Universidad de Iowa generalmente requieren que documentemos su participación en investigaciones que se realizan en un centro de atención médica de la Universidad de Iowa. Esta documentación estará en su registro médico o en una base de datos mantenida en nombre de la institución que refleje que está participando en este estudio. La información incluida proporcionará información de contacto para el equipo de investigación, así como información sobre los riesgos asociados con este estudio. Adicionalmente, mantendremos este Documento de Consentimiento en nuestros archivos de investigación; no se colocará en su registro médico.

¿SE UTILIZARÁ MI INFORMACIÓN DE SALUD DURANTE ESTE ESTUDIO?

La Ley Federal de Portabilidad y Responsabilidad de Seguros de Salud (HIPAA, por sus siglas en inglés) requiere que University of Iowa Health Care obtenga su permiso para que el equipo de investigación acceda o cree "información médica protegida" sobre usted para los fines de este estudio de investigación. La información de salud protegida es información que lo identifica personalmente y se relaciona con su condición, cuidado de salud mental o física pasada, presente o futura. Accederemos o crearemos información médica sobre usted, tal como se describe en este documento, para los fines de este estudio de investigación y por su tratamiento. Una vez que la Universidad de Iowa Health Care nos haya revelado su información médica protegida, es posible que ya no esté protegida por las regulaciones federales de privacidad de HIPAA, pero continuaremos protegiendo su confidencialidad como se describe en la sección "Confidencialidad".

Podemos compartir su información de salud relacionada con este estudio con otras partes, incluidas las agencias reguladoras del gobierno federal, las Juntas de Revisión Institucional de la Universidad de Iowa y el personal de apoyo.

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No puede participar en este estudio a menos que nos permita usar su información de salud protegida. Si elige no permitirnos que usemos su información médica protegida, discutiremos cualquier alternativa de no investigación disponible para usted. Su decisión no afectará su derecho a la atención médica que no esté relacionada con la investigación. Su firma en este Documento de consentimiento autoriza a University of Iowa Health Care a darnos permiso para usar o crear información médica sobre usted.

Aunque es posible que no se le permita ver la información del estudio hasta después de que finalice este estudio, se le puede dar acceso a sus registros de atención médica comunicándose con su proveedor de atención médica. Su permiso para acceder o crear información médica protegida sobre usted para los fines de este estudio no tiene fecha de vencimiento. Puede retirar su permiso para que usemos su información de salud para este estudio de investigación enviando un aviso por escrito a Linea Polgreen, College of Pharmacy, 115 S Grand Ave. #S512, Iowa City, Ia 52242. Sin embargo, todavía podemos utilizar su información de salud que se recogió antes de retirar su permiso. También, si hemos enviado su información de salud a terceros, como el patrocinador del estudio, o nos hemos quitado su información de identificación, puede no ser posible evitar su uso futuro. Usted recibirá una copia de este documento firmado.

¿ESTAR EN ESTE ESTUDIO ES VOLUNTARIO?

Participar en este estudio de investigación es completamente voluntario. Puede optar por no participar. Si decide participar en este estudio, puede dejar de participar en cualquier momento. Si decide no participar en este estudio, o si deja de participar en cualquier momento, no se lo penalizará ni perderá ningún beneficio por el cual reúna los requisitos.

¿QUÉ SUCEDE SI DECIDO ABANDONER EL ESTUDIO?

Si decide abandonar el estudio temprano, le pediremos que se comunique con el equipo de investigación al 319-775-0689.

¿QUÉ PASA SI TENGO PREGUNTAS?

Le animamos a hacer preguntas. Si tiene alguna pregunta sobre el estudio de investigación, comuníquese con Shelby Francis (319-678-8037, Shelby-francis@uiowa.edu). Si experimenta una lesión relacionada con la investigación, comuníquese con Linnea Polgreen (319-384-4091).

Si tiene preguntas, preocupaciones o quejas sobre sus derechos como sujeto de investigación o sobre lesiones relacionadas con la investigación, comuníquese con la Oficina de Sujetos Humanos, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, o correo electrónico irb@uiowa.edu. Puede encontrar información general sobre cómo ser un sujeto de investigación haciendo clic en "Información para público" en el sitio web de la Oficina de Asuntos Humanos, http://hso.research.uiowa.edu/. Para ofrecer comentarios sobre sus experiencias como sujeto de investigación o para hablar con alguien que no sea el personal de investigación, llame a la Oficina de Sujetos Humanos al número que aparece arriba.

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Este Documento de Consentimiento Informado no es un contrato. Es una explicación por escrito de lo que sucederá durante el estudio si decide participar. No está renunciando a ningún derecho legal al firmar este Documento de consentimiento informado. Su firma indica que se le ha explicado este estudio de investigación, que sus preguntas han sido respondidas y que usted acepta participar en este estudio. Recibirá una copia de este formulario.

Nombre del sujeto (imprimido): _____

_____ _____
(Firma del sujecto) (Fecha)

Declaración de Persona Quien Obtenio Consentimiento

He hablado de los susodichos puntos con el sujeto o, donde asignado, con el representante legalmente autorizado del sujeto. Esto es mi opinión que el sujeto entiende los riesgos, beneficios, y procedimientos implicados con la participación en este estudio de investigación.

_____ _____
(Firma de Persona quien Obtenio Consentimiento) (Fecha)

Appendix 5: Baseline REDCap Form

Baseline Data

Record ID _____

Date of Baseline Measures _____

Research Blood Pressure Measurements:

--Prepare the Participant--
***No smoking 20 minutes prior to BP measurement**
***Remove all clothing that covers the location of cuff placement**
*** Sit comfortably in a chair, with back supported, legs uncrossed and flat on floor, arm supported at level of the heart on table, palm facing upward**
***Sit for at least 5 minutes before first measurement; relax as much as possible**

--Cuff Measurement--
*** Choose cuff that fits arm circumference you previously measured. If arm measurement falls on number that is specified for 2 cuffs, both cuffs should be placed on arm sequentially and the cuff for which the INDEX arrow that is marked on the cuff best falls within the range bar should be chosen**

--Cuff Placement--
***Do not allow a sleeve to form a tourniquet on the arm**
***Palpate the brachial artery in the antecubital fossa and place the ART arrow that is marked on the midline of the bladder of the cuff so that it is over the arterial pulsation of the participant's bare arm**
*** The lower end of the cuff should be 1/2 to 1 inch above the inner side of the elbow joint**
***The middle of the cuff should be at the level of the right atrium**
*** Place the cuff snugly around the bare upper arm so that you can only insert one finger between the cuff and the arm**

--BP Measurement--
***Use the Omron HEB-907-XL**
***Tell the participant you will be taking 3-4 measurements and that neither of you should talk during the measurement time**
***Take first measurement and record (this value will be ignored). Wait 60 seconds before taking next measurement**
***Take second measurement and record. Wait 60 seconds before taking next measurement**
***Take third measurement and record. If 2nd and 3rd values are more than 4 mmHg apart, take a 4th reading.**
***The two nearest values (of 2-4) will be averaged. If the average value is less than 145 or 95, the person NOT eligible to continue with the study. Thank them for their time.**

If you get an error message at any point, start the sequence over!

1st Blood Pressure (this value is ignored)	
Baseline SBP #1	_____
Baseline DBP #1	_____
2nd Blood Pressure	
Baseline SBP #2	_____
Baseline DBP #2	_____ (If average BP value is less than 145 or 95, the patient is NOT eligible.)
3rd Blood Pressure	
Baseline SBP #3	_____
Baseline DBP #3	_____ (If average BP value is less than 145 or 95, the patient is NOT eligible.)
4th Blood Pressure (only needed if the 2nd and 3rd measurements are more than 4 mmHg apart.)	
Baseline SBP #4	_____
Baseline DBP #4	_____ (If average BP value is less than 145 or 95, the patient is NOT eligible.)
Patient Contact Information	
Phone Number	_____
Permission to Text the Above Number	◯ yes ◯ no
Email Address	_____
Street Address	_____ (needed for compensation checks)

City, State, Zip

_____
(needed for compensation checks)

Distance from participant's home to clinic (miles)

_____
(This field can be calculated after the appointment.)

Additional Contact Information

This person will only be contacted if we have trouble reaching the participant. We will not tell the contact person details about the study, just that the participant is enrolled in a research study at the University of Iowa and has listed them as someone who will know how to reach them.

Relationship to Participant

_____

Contact Name

_____

Contact Phone Number

_____

Demographic Information

Race

- ◯ American Indian or Alaska Native
- ◯ Asian
- ◯ Black or African American
- ◯ Native Hawaiian or Other Pacific Islander
- ◯ White
- ◯ Multiracial
- ◯ Other

Ethnicity

- ◯ Hispanic
- ◯ Non-Hispanic
- ◯ Unknown

If other, please specify

_____

Sex

- ◯ Male
- ◯ Female
- ◯ Other

If other, please specify

_____

Insurance

- ☐ Private (Insurance through employer or self-purchased)
- ☐ State insurance/Medicaid
- ☐ Federal insurance/Medicare
- ☐ Uninsured

Level of Education	◯ < High school ◯ High school diploma or GED ◯ Some college or trade school ◯ Associate's degree ◯ Bachelor's degree ◯ Master's degree ◯ Doctorate or Professional Degree ◯ Trade license or certification
Marital Status	◯ Never married ◯ Married ◯ Living as married ◯ Divorced or separated ◯ Widowed

Smoking Behaviors

Smoking Status	◯ Never smoked ◯ Current smoker ◯ Ex-smoker
Number of Years Smoked	_____
Number of Cigarettes Smoked Per Day	_____
Years Since Quit Smoking	_____

Smokeless Tobacco Behaviors

Smokeless Tobacco Status	◯ Never used ◯ Current user ◯ Ex-user
Number of Years Using Smokeless Tobacco	_____
Number of Snuffs/Dips/Chews Per Day?	_____
Years Since Quit Smokeless Tobacco	_____

Alcohol Behaviors

How often do you have a drink containing alcohol?	◯ Never ◯ Monthly or less ◯ 2-4 times a month ◯ 2- 3 times a week ◯ 4 or more times a week

How many drinks containing alcohol do you have a on a typical day when you are drinking?	◯ 1 or 2 ◯ 3 or 4 ◯ 5 or 6 ◯ 7, 8, or 9 ◯ 10 or more

Other Issues

Any History of These Issues	☐ Angina ☐ Anxiety ☐ Arthritis ☐ Asthma ☐ Cancer ☐ Chronic Kidney Disease ☐ Chronic Obstructive Pulmonary Disease (COPD) ☐ Coronary Artery Disease (CAD) ☐ Depression ☐ Diabetes ☐ Heart Failure ☐ Hyperlipidemia ☐ Liver Disease ☐ MI (heart attack) ☐ Peripheral Artery Disease (PAD) ☐ Seizures ☐ Stroke ☐ TIA (transient ischemic attack) ☐ None
Notes about Other Issues	_____
Research intern who collected baseline data.	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis

Appendix 6: BP Medications

Baseline BP Medications

Record ID	_____
BP Medication Code	_____
BP Medication Name	_____
Times/Day	_____ (How many times is this medication taken per day? (1, 2, 3, etc.))
Medication Notes	_____
Research intern who obtained baseline medications.	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis

Appendix 7: Drug Codes for Antihypertensive Agents

Diuretics – *Class Code = 100*

Code	Generic Name	Brand Names	Strengths Available
101	amiloride	Midamor	5 mg
102	amiloride/hydrochlorothiazide*	Moduretic	5/50 mg
103	bumetanide	Bumex	0.5 mg, 1 mg, 2 mg
104	chlorothiazide	Diuril	250 mg, 500 mg
105	chlorthalidone	Hygroton and others	25 mg, 50 mg, 100 mg
106	furosemide	Lasix	20 mg, 40 mg, 80 mg
107	hydrochlorothiazide	Hydrodiuril & others	12.5 mg, 25 mg, 50 mg
108	triamterene/hydrochlorothiazide*	Dyazide, Maxide	37.5/25 mg, 50/25 mg, 75/50 mg
109	indapamide	Lozol	1.25 mg, 2.5 mg
110	metolazone	Mykrox, Zaroxolyn	2.5 mg, 5 mg, 10 mg
111	polythiazide	Renese	1 mg, 2 mg, 5 mg
112	spironolactone/hydrochlorthiazide*	Aldactazide	25/25 mg, 50/50 mg
113	torsemide	Demadex	5 mg, 10 mg, 20 mg, 100 mg
114	triamterene	Dyrenium	50 mg, 100 mg
115	Ethacrynic acid	Edecrin	25 mg

* list specific strength of each ingredient

Beta Blockers – *Class Code = 200*

Code	Generic Name	Brand Names	Strengths Available
201	acebutolol	Sectral	200 mg, 400 mg
202	atenolol	Tenormin	25 mg, 50 mg, 100 mg
203	betaxolol	Kerlone	10 mg, 20 mg
204	bisoprolol	Zebeta	5 mg, 10 mg
205	metoprolol tartrate	Lopressor	25 mg, 50 mg, 100 mg
206	metoprolol succinate (extended release)	Toprol XL	25 mg, 50 mg, 100 mg, 200 mg
207	nadolol	Corgard	20 mg, 40 mg, 80 mg, 120 mg, 160 mg
208	penbutolol	Levatol	20 mg
209	pindolol	Visken	5 mg, 10 mg
210	propranolol	Inderal	10 mg, 20 mg, 40 mg, 60 mg, 80 mg
211	propranolol long-acting	Inderal LA	60 mg, 80 mg, 120 mg, 160 mg
212	timolol	Blocadren	5 mg, 10 mg, 20 mg
213	atenolol-chlorthalidone	Tenoretic	50/25 mg, 100/25 mg
214	bisoprolol-hydrochlorothiazide*	Ziac	2.5/6.25 mg, 5/6.25 mg, 10/6.25 mg
215	metoprolol-hydrochlorothiazide*	Lopressor HCT	50/25 mg, 100/25 mg, 100/50 mg
216	nadolol-bendroflumethiazide*	Corzide	40/5 mg, 80/5 mg
217	propranolol LA- hydrochlorothiazide*	Inderide LA	40/25 mg, 80/25 mg
218	timolol-hydrochlorothiazide*	Timolide	10/25 mg
219	Nebivolol	Bystolic	2.5 mg, 5 mg, 10 mg, 20 mg
220	metoprolol succinate	Dutoprol HCTZ	25/12.5 mg, 50/12.5 mg, 100/12.5 mg

* list specific strength of each ingredient

Alpha/Beta Blockers *Class Code = 200*

Code	Generic Name	Brand Names	Strengths Available
220	carvedilol	Coreg	3.125 mg, 6.25 mg, 12.5 mg, 25 mg
221	labetalol	Normodyne, Trandate	100 mg, 200 mg, 300 mg
222	carvedilol extended release	Coreg CR	10 mg, 20 mg, 40 mg, 80 mg

ACE Inhibitors – *Class Code = 300*

Code	Generic Name	Brand Names	Strengths Available
301	benazepril	Lotensin	5 mg, 10 mg, 20 mg, 40 mg
302	captopril	Capoten	12.5 mg, 25 mg, 50 mg, 100 mg
303	enalapril	Vasotec	2.5 mg, 5 mg, 10 mg, 20 mg
304	fosinopril	Monopril	10 mg, 20 mg, 40 mg
305	lisinopril	Zestril, Prinivil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
306	moexipril	Univasc	7.5 mg, 15 mg
307	perindopril	Aceon	2 mg, 4 mg, 8 mg
308	quinapril	Accupril	5 mg, 10 mg, 20 mg, 40 mg
309	ramipril	Altace	1.25 mg, 2.5 mg, 5 mg, 10 mg
310	trandolapril	Mavik	1 mg, 2 mg, 4 mg
311	benazepril-hydrochlorothiazide*	Lotensin HCT	5/6.25 mg, 10/12.5 mg, 20/12.5 mg, 20/25 mg
312	captopril-hydrochlorothiazide*	Capozide	25/15 mg, 25/25 mg, 50/15 mg, 50/25 mg
313	enalapril-hydrochlorothiazide*	Vaseretic	5/12.5 mg, 10/25 mg
314	fosinopril-hydrochlorothiazide*	Monopril-HCT	10/12.5 mg, 20/12.5 mg
315	lisinopril-hydrochlorothiazide*	Prinzide, Zestoretic	10/12.5 mg, 20/12.5 mg, 20/25 mg
316	moexipril-hydrochlorothiazide*	Uniretic	7.5/12.5 mg, 15/12.5 mg, 15/25 mg
317	quinapril-hydrochlorothiazide*	Accuretic	10/12.5 mg, 20/12.5 mg, 20/25 mg

* list specific strength of each ingredient

Calcium Channel Blockers – *Class Code = 400*

Code	Generic Name	Brand Names	Available Strengths
401	amlodipine	Norvasc	2.5 mg, 5 mg, 10 mg
402	diltiazem	Cardizem, Dilacor, Tiazac	30 mg, 60 mg, 90 mg, 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 420 mg
403	felodipine	Plendil	2.5 mg, 5 mg, 10 mg
404	isradipine	DynaCirc	2.5 mg, 5 mg, 10 mg
405	nicardipine	Cardene	20 mg, 30 mg, 45 mg, 60 mg
406	nifedipine	Adalat, Procardia	10 mg, 20 mg, 30 mg, 60 mg, 90 mg
407	nisoldipine	Sular	8.5 mg, 10 mg, 17 mg, 20 mg, 25.5 mg, 30 mg, 34 mg, 40 mg
408	verapamil	Calan, Isoptin, Verelan, Coer, Covera HS	40 mg, 80 mg, 100 mg 120 mg, 200 mg, 180 mg, 240 mg, 300 mg, 360 mg

ACE Inhibitor/Calcium Channel Blocker Combinations *Class Code = 300, 400*

Code	Generic Name	Brand Names	Available Strengths
410	amlodipine/benazepril*	Lotrel	2.5/10 mg, 5/10 mg, 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg
411	enalapril/felodipine *	Lexxel	5/2.5 mg, 5/5 mg
412	trandolapril/verapamil*	Tarka	1/240 mg, 2/180 mg, 2/240 mg, 4/240 mg
413	perindopril/amlodipine	Prestalia	3.5/2.5 mg, 7/5 mg, 14/10 mg

* list specific strength of each ingredient

Calcium Channel Blocker:Angiotensin II Receptor Blocker Combination
Class Code = 400, 600

Code	Generic Name	Brand Names	Available Strengths
420	amlodipine/valsartan*	Exforge	5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg
421	amlodipine/valsartan/hydrochlorothiazide	Exforge HCT	5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg
422	amlodipine/olmesartan	AZOR	5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg
423	Telmisartan/amlodipine	Twynsta	40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg

* list specific strength of each ingredient

Alpha blockers – *Class Code = 500*

Code	Generic Name	Brand Names	Available Strengths
501	doxazosin	Cardura	1 mg, 2 mg, 4 mg, 8 mg
502	prazosin	Minipress	1 mg, 2 mg, 5 mg
503	terazosin	Hytrin	1 mg, 2 mg, 5 mg, 10 mg
504	prazosin/polythiazide	Minizide	1/0.5 mg, 2/0.5 mg, 5/0.5 mg

Angiotensin II receptor antagonists (ARB) – *Class Code = 600*

Code	Generic Name	Brand Names	Available Strengths
601	candesartan	Atacand	4 mg, 8 mg, 16 mg, 32 mg
602	eprosartan	Teveten	400 mg, 600 mg
603	irbesartan	Avapro	75 mg, 150 mg, 300 mg
604	losartan	Cozaar	25 mg, 50 mg, 100 mg
605	olmesartan	Benicar	5 mg, 20 mg, 40 mg
606	telmisartan	Micardis	20 mg, 40 mg, 80 mg
607	valsartan	Diovan	40 mg, 80 mg, 160 mg, 320 mg
608	candesartan-hydrochlorothiazide	Atacand HCT	16/12.5 mg, 32/12.5 mg, 32/25 mg
609	eprosartan-hydrochlorothiazide	Teveten-HCT	600/12.5 mg, 600/25 mg
610	irbesartan-hydrochlorothiazide	Avalide	150/12.5 mg, 300/12.5 mg, 300/25 mg
611	losartan-hydrochlorothiazide	Hyzaar	50/12.5 mg, 100/12.5 mg, 100/25 mg
612	olmesartan medoxomil-hydrochlorothiazide	Benicar HCT	20/12.5 mg, 40/12.5 mg, 40/25 mg
613	telmisartan-hydrochlorothiazide	Micardis-HCT	40/12.5 mg, 80/12.5 mg, 80/25 mg
614	valsartan-hydrochlorothiazide	Diovan-HCT	80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, 320/25 mg
615	Azilsartan Medoxomil	Edarbi	40 mg, 80 mg

Centrally Acting Alpha 2 blockers – *Class Code = 700*

Code	Generic Name	Brand Names	Strengths Available
701	clonidine	Catapres	0.1 mg, 0.2 mg, 0.3 mg
702	clonidine topical patch	Catapres TTS	0.1 mg, 0.2 mg, 0.3 mg
703	guanabenz	Wytensin	4 mg, 8 mg
704	guanfacine	Tenex	1 mg, 2 mg
705	methyldopa	Aldomet	250 mg, 500 mg
706	methyldopa-hydrochlorothiazide	Aldoril	250/15 mg, 250/25 mg
707	clonidine-chlorthalidone	Clorpres	0.1/15 mg, 0.2/15 mg, 0.3/15 mg

* list specific strength of each ingredient

Peripheral Adrenergic Blocking Agents – *Class Code = 800*

Code	Generic Name	Brand Names	Strengths Available
801	reserpine		0.1 mg, 0.25 mg
802	reserpine-chlorthalidone	Demi-Regroton	
803	reserpine-chlorothiazide	Diupres	
804	reserpine-hydrochlorothiazide	Hydropres	0.125/25 mg, 0.125/50 mg
805	Ser Ap Es		

Vasodilators – *Class Code = 900*

Code	Generic Name	Brand Names	Strengths Available
901	hydralazine	Apresoline	10 mg, 25 mg, 50 mg, 100 mg
902	isosorbide dinitrate	Isordil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
903	isosorbide mononitrate	Imdur	10 mg, 20 mg, 30 mg, 60 mg, 120 mg
904	minoxidil	Loniten	2.5 mg, 10 mg
905	hydralazine-hydrochlorothiazide		25/25 mg, 50/50 mg, 100/50 mg
906	isosorbide dinitrate-hydralazine	BiDil	20/37.5 mg

* list specific strength of each ingredient

Aldosterone Receptor Blockers – *Class Code = 1000*

Code	Generic Name	Brand Names	Strengths Available
1001	eplerenone	Inspra	25 mg, 50 mg
1002	spironolactone	Aldactone	25 mg, 50 mg, 100 mg

* list specific strength of each ingredient

Direct Renin Inhibitor – *Class Code = 2000*

Code	Generic Name	Brand Names	Strengths Available
2001	aliskiren	Tekturna	150 mg, 300 mg
2002	aliskiren-hydrochlorothiazide	Tekturna HCT	150/12.5 mg, 150/25 mg, 300/12.5 mg, 300/25 mg
2003	aliskiren-valsartan	Valturna	150/160 mg, 300/320 mg

Appendix 8: Compensation Form

Baseline Compensation

Record ID	_____
Compensation Date	_____
Compensation Amount	_____
Voucher Number	_____
Compensation Intern	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki
Notes	_____

Appendix 9: Group Assignment REDCap Form

Group Assignment

Record ID	_____
Participant was assigned to	◯ Intervention group ◯ Control group

Appendix 10: Pharmacist REDCap Forms

Scheduling Call

Record ID _____

Date of Scheduling Call

_____

Time of Scheduling Call

_____

Encounter Outcome

- ◯ Complete - spoke with patient
- ◯ Complete - spoke with proxy
- ◯ Complete - revised appointment date/time
- ◯ Incomplete - no answer, left message
- ◯ Incomplete - busy signal/no voicemail
- ◯ Incomplete - wrong number

Note

Follow Up

Date

_____

Time

_____

Form Author

_____

Patient Follow Up

Record ID

Encounter Date

Contact Type

◯ Patient ◯ Other (explain in comments below)

Contact Type Comments:

Encounter Length

(minutes)

Encounter Notes

Barriers/Side Effects

Barriers to Regimen/Side Effects

Adherence

of missed doses in the past week

Use of adherence tools

Medication cost concerns

Assessment/Plan

BP Goal

Patient is/is not at goal.

- ○ is
- ○ is not

Lifestyle Changes Recommended to Patient

Lifestyle changes recommended to patient: (check all that apply)

- ☐ decrease weight
- ☐ DASH plan
- ☐ Other diet recommended
- ☐ reduce sodium
- ☐ increase activity
- ☐ decrease smoking
- ☐ increase med compliance
- ☐ other
- ☐ no lifestyle changes recommended

If other, specify here:

_____

New Plan/Recommendations

New plan/recommendations

- ○ Continue current regimen
- ○ Recommend change to plan

If recommending change to plan, list complete plan here:

_____

Include:
1) Prescribed medication
2) Medication code
3) Change Type (a = drug started, b = dose increased, c = dose decreased, d = drug discontinued)
4) Dose 1
5) Dose 2
6) Unit
7) Frequency
8) Comments

Follow Up Information (if applicable)

Date

_____

Follow Up Time

_____

Follow up purpose:

Form Author

Physician Communication

Record ID

_____

Encounter Date

_____

Encounter Mode

◯ EMR ◯ Email ◯ Fax ◯ Other (explain in comments below)

Encounter Comments

Provider Name

_____

Physician Acceptance

◯ Recommended plan accepted ◯ Recommended plan modified (list complete final plan below)
◯ Plan not accepted, continue previous plan

Final Plan (complete only if changed from pharmacist recommended plan)

Include:
1) Prescribed medication
2) Medication code
3) Change Type (a = drug started, b = dose increased, c = dose decreased, d = drug discontinued)
4) Dose 1
5) Dose 2
6) Unit
7) Frequency
8) Comments

Recommendation Outcome Date

_____

Follow Up Information (if applicable)

Date

_____

Time

_____

Form Author

_____

Appendix 11: 12 Month Exit Survey

12 Month Exit Survey

Record ID _____

Blood Pressure Measurement

How difficult was it for you to measure your blood pressure?

- ○ Extremely difficult
- ○ Difficult
- ○ Neutral
- ○ Easy
- ○ Extremely easy
- ○ I prefer to not answer

How difficult was it for you to text us your blood pressure values?

- ○ Extremely difficult
- ○ Difficult
- ○ Neutral
- ○ Easy
- ○ Extremely easy
- ○ I prefer to not answer

How often would you be willing to continue text your blood pressure values to your health care provider?

- ○ Once per day
- ○ Once per week
- ○ Once per month
- ○ Once every 3 months
- ○ Once every year
- ○ I prefer to not answer

Pharmacist Questions

My contact(s) with the research pharmacist were

- ○ Extremely unhelpful
- ○ Unhelpful
- ○ Neutral
- ○ Helpful
- ○ Extremely helpful
- ○ I prefer to not answer

I would find it helpful to continue having contact with the research pharmacist after the study is over.

- ○ Yes
- ○ No
- ○ Unsure
- ○ I prefer to not answer

Feedback Responses

What suggestions do you have about the process of measuring your blood pressure and texting it to us?

_____

What problems, if any, did you have measuring and texting your blood pressure values?

_____

What feedback do you have about the research pharmacist?

_____

Appendix 12: Patient-Reported ER Visits or Hospitalizations

Patient-Reported ER Visits or Hospitalizations

Record ID	_____
Has the patient had any emergency room visits or been hospitalized during the 12 months of study follow up outside of the University of Iowa system?	
Diagnosis/Reason	_____ (Record N/A if patient did not have any visits during this time.)
Date	_____
Research intern who collected outside visits/hospitalizations.	◯ Brady Lutney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis

Appendix 13: Clinic/Quick Care Visits, Emergency Room Visits, and Hospitalizations

Clinic/Quick Care Visits

Record ID	_____
Diagnosis	_____ (Record N/A if patient did not have any visits during this time.)
Date of Visit	_____
Research intern who recorded visits	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis

Emergency Room Visits

Record ID	_____
Diagnosis	_____ (Record N/A if patient did not have any visits during this time.)
Date	_____
Research intern who recorded emergency room visits.	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis

Hospitalizations

Record ID	_____
Diagnosis	_____ (Record N/A if patient did not have any hospitalizations during this time.)
Date Admitted	_____
Number of Days Hospitalized	_____
Research intern who recorded hospitalizations.	◯ Brady Letney ◯ Trey Krupp ◯ Michael Bielecki ◯ Miguel Gutierrez ◯ Alec Hanson ◯ Shelby Francis