PROTOCOL TITLE: Evaluating the Effect of an Evidence-Based One Page with Supplemental Visual Aids on the Knowledge and Perceptions of Blood Pressure Management Among Adults with Hypertension

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PRINCIPAL INVESTIGATOR:

Alexandra Herman, PharmD

Department of Pharmacy Practice & Administrative Sciences

VERSION NUMBER:

1.0

DATE:

8/10/20

REGULATORY FRAMEWORK:

Please indicate all that apply: Not Applicable

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

This protocol is unfunded.

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or

subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

Table of Contents

1. Objectives

1.1 To evaluate changes in patient knowledge of blood pressure management and perceptions of making lifestyle changes to manage their blood pressure after implementation of an evidence-based one-page teaching protocol with supplemental handouts and optional use of suggested apps and web sites.

1.2 The working hypothesis is that patients will improve their knowledge of blood pressure management and have more positive perceptions of making evidence-based lifestyle changes to manage their blood pressure after receiving education from PharmD students using a one-page teaching protocol with supplemental visual aids and optional use of suggested apps and web sites.

2. Background

2.1 Hypertension (HTN) affects as many as one in three adults in the United States (US); of those approximately 50 percent are managing their blood pressure in accordance with national guideline goals (Rodriguez, Friedberg, DiGovanni, Want, Whilie-Rosett, Hyound, & Natarajan, 2019). There are many comorbid conditions that come with HTN such as end-stage kidney disease, stroke, or heart attack (Rodriguez et al., 2019). Not only does living with untreated HTN lead to associated comorbid conditions that decrease the quality of life, but it also contributes to an astronomical cost the health care system to manage additional disease burden. Annual costs related to hypertension health care dollars has been reported as high as $55.9 billion (Benjamin et al., 2019).

2.2 There has been confusion among health care providers over optimal blood pressure management due to discordance in national guidelines. The Joint National Committee 7 guideline (JNC7) recommended treatment of high blood pressure regardless of age if blood pressure was greater than 140/90 (Lenfant, Chobanian, Jones, & Roccella, 2003). JNC8 was considered to have "relaxed" the guidelines on early detection which would affect initiating treatment for people (not initiating treatment until systolic was over 150 if over age 60) (Armstrong, 2014). The ACC/AHA/AAPA/ABC/ACPM/AGA/AphA/ASH/ASPC/NMA/PCNA Guideline helps reconcile this variance between the two standards while providing a very extensive road map on how to manage adults with HTN in all aspects of care (Whelton et al., 2018).
There have been strides made to decrease disparities in treatment for ethnic minorities, however, there remains a 33 percent higher death rate for non-Hispanic blacks (NHB) for non-Hispanic blacks (NHB) for cardiovascular disease in the U.S. (Balfour, Rodriquez, & Ferdinand, 2015). This is addressed in the 2017 ACC/AHA

Guideline with specific guidelines on appropriate treatment and management of hypertension for minority populations (Whelton et al., 2018). New Mexico is a diverse and unique minority-majority state, making it necessary for clinicians/students to understand key treatment differences based on ethnicity. The 2017 ACC/AHA guideline also recommends HTN management to be provided in a collaborative manner (Whelton et al., 2018). The Million Hearts Initiative is a method adopted by many schools and facilities in the US (Gawlik & Melnyk, 2015) with the goal to prevent 1 million heart attacks and strokes by 2017. While 2017 has come and gone, this project is still being used to set the stage for population-driven health care accomplished through a collaborative team of health care providers (Gawlik & Melnyk, 2015). The Centers for Disease Control (CDC) and Prevention recognize the value of the role of the pharmacist improving blood pressures in the community from a population health perspective. With the ever increasing aging population, the CDC created a comprehensive resource guide for pharmacists to use in order to improve blood pressure management in communities (Di Palo & Kish, 2018). There is strong published evidence/data that supports the critical role pharmacist play to improve hypertension management which includes: medication management, patient-centered counseling, and disease state education (Di Palo, & Kish, 2018). A well-established understanding in research is from the time of findings to implementation of findings there can be a span of 15 years or greater before the general medical community implements the most recent evidenced-based guidelines (White, Dudley-Brown, & Terhaar, 2016). This study will add to the body of existing knowledge on how well patients with hypertension understand the new blood pressure goal which is lower than previous guidelines. In other words, is the medical community translating evidence three years out from the most recent guideline update in 2017 well or not?

2.3 A problem for blood pressure management specific to New Mexico is the lack primary care and specialty to identify and manage HTN. Many clinics are not accepting new patients due to provider shortages (Abundis, 2019). New Mexico is a poor state with over 50 percent of the population on some form of government assistance (Domrzalski, 2014). Those in a lower socio economic status (SES) may have difficulty with access to care, transportation to appointments, or paying for their medications. Additional research is needed on modes of improving blood pressure management in the setting of these provider shortages and health disparities. Pharmacists are ideally positioned in the community as part of the care team by reinforcing patient-centered teaching on hypertension education. An example used in pharmacies are telephonic follow-ups or telehealth (text reminders for prescription pick up as an example) (Di Palo & Kish, 2018).
Shared decision making (SDM) is recommended in one of the latest clinical guidelines to improve adherence to recommendations made by the clinician in order to improve patient's agreement to follow through on given recommendations during

the encounter (Langford et al., 2019). The recognition of cultural differences in preferences for treatment is imperative in order to improve the disparity in care, and thereby improve blood pressure numbers for all adults in the US regardless of their ethnicity. Using the model of SDM has shown benefit for patient compliance (Langford et al., 2019).

Using the latest blood pressure guidelines set forth by the 2017 ACC/AHA recommendations (Whelton et al., 2018), and the Million Hearts Initiative guidelines (Gawlik & Melnyk, 2015) a comprehensive "one-page" with supplemental visual aids will be used. The one-page will be in the format of a single page, double sided hand-out that covers: medications to avoid that can increase blood pressure, and self-monitoring with the American Heart Association visual aide of how to take blood pressure on the front side. The back-side will have information on: diet, smoking cessation, and physical activity. The diet section will have a visual aid from the National Heart, Lung, and Blood Institute specific to the DASH diet recommended from the 2017 ACC/AHA guideline (Whelton et al., 2018). The smoking cessation will be addressed with the National 1-800-Quit-Now number with the participant encourage to have a separate appointment with their PCP should this be a primary focus for them. For the purpose of this study, smoking cessation assistance requires more allocated time that what is planned for each participant. The exercise section will have a visual aid from the American Heart Association about proper type of exercise and length of time to exercise. There will be a table provided for quick reference with evidenced based recommended websites and apps for the participant should they have access to the internet. These handouts are included with this submission. The one-page document is included with the submission as "My Planned Behavior for Managing my Blood Pressure."

3. Study Design

3.1. Study design: prospective clinical trial with human participants assigned to an intervention of a one-page handout with supplemental visual aids and optional use of suggested apps and websites as an educational intervention to improve their knowledge of blood pressure management through behavior changes recommended to them.

3.2. N/A. There will be no blinding in this study.

4. Inclusion and Exclusion Criteria

4.1. Patients will be screened with an initial interview which will be conducted over the phone. The interview script is included in this submission as "UNM HTN Phone Screen for Potential Participants." Their Walgreens medication profile will also be reviewed to verify that they are on medications for hypertension.

4.2. The inclusion criteria will be: adults from 18 to 75 years old, ability to self-consent, English-speaking, able to read/write English, currently prescribed at least one medication for treatment of essential primary hypertension.

4.3. There will be no special populations in this study. This study will not include adults unable to consent; individuals who are not yet adults (infants, children, teenagers); pregnant women; or prisoners.

4.4. Pregnant women will be excluded due to the complexity of hypertension in pregnancy, which warrants management by an OB/GYN or other specialists. Potential participants will be asked if they are pregnant or planning to become pregnant using the screening document "UNM HTN phone screen for potential patients." Children are excluded for three reasons: 1) the writer is only certified as an NP to work with adults; 2) the focus of this study is the population at greatest risk for high blood pressure which is adults; and 3) children with high blood pressure are rarely diagnosed with essential primary hypertension, and should be managed by a specialist. We do not have the resources to provide adequate materials in Spanish or other languages commonly spoken in NM, and further research may be needed on the effect of the intervention for non-English speaking patients.

5. Number of Subjects

5.1. This is a single site study and will be done at one location, Walgreens Store #6587 in Albuquerque, New Mexico. There will be 50 participants recruited.

5.2. The number to be recruited will be 50.

5.3. Based on statistical analysis from UNM Statistics Department, a sample size of at least 45 patients is needed. The number to be recruited at the onset will be 50 to account for attrition.

6. Study Timelines

6.1.

- Duration of individual's participation in research: The total expected duration of participants' active participation is less than 60 minutes. The participants will have mailed to them at the start of the study: one-page with supplemental handouts/visual aids, list of suggested apps and web sites, pre/post survey and pre/post-test with self-addressed stamped envelopes (SASE) to return their information, and a pill box.
- Recruitment for this study will begin August-September 2020. Duration anticipated to enroll all subjects: 30 days
- Total duration for researchers to complete the study: Recruitment will occur through end of Sept 2020; additional follow-up phone calls will occur through

September-November 2020. Data analysis will occur during the month of December 2020. Manuscript preparation and submission to scholarly publications will occur shortly thereafter with the target of January 2021.

7. Study Endpoints

7.1. Primary endpoint: change in participant's knowledge of blood pressure management; change in participant's perception of making lifestyle changes to manage their hypertension

7.2. Describe any primary or secondary safety endpoints: N/A

7.3. Describe any exploratory endpoints:
1: Participants will be asked to rate the usefulness, ease of reading, and attractiveness/visual appeal of each handout they were provided.
2: Participants who choose to use any apps or web sites will be asked for feedback on usefulness, ease of reading/access, and attractiveness/visual appeal for each app or web site used.
3: The subset of participants who choose to use electronic resources will be compared to the subset of participants who do not to compare any differences in the primary outcome.

8. Research Setting

8.1. Site or location: Walgreens Store #6587 in Albuquerque, NM.

8.2. We will recruit potential subjects from Walgreens Store #6587 in Albuquerque, NM. Participants will be recruited over the phone.

8.3. Research will be performed from Walgreens Store #6587 in Albuquerque, NM.

8.4. Describe the composition and involvement of any community advisory board: N/A

8.5. This is a partnership with UNM College of Pharmacy, Walgreens Pharmacy, and a Doctor of Nursing (DNP) student enrolled in the DNP program at Missouri State University (MSU). Per MSU policy, once the IRB is submitted and approved through UNM, the IRB approval from UNM with a summary paragraph will be submitted to MSU for record. Carla R. Kychik, DNP candidate, will be responsible for submitting the approved UNM IRB with summary paragraph to the MSU IRB board to complete this requirement. A cede letter is included in this submission.

9. Resources Available

9.1. The PI is Dr. Alexandra Herman, PharmD with UNM College of Pharmacy, who has completed a two-year fellowship in Cardiovascular Pharmacotherapy and holds a Certificate in Clinical & Translational Research.

Carla R. Kychik, MSN, ANP-C (certification for adult care) is completing this project as part of a DNP program at MSU. She will be responsible for diagnosing, managing care, ordering labs/diagnostics, and referrals to specialty care. She has completed board certification by the American Nurse Association for Cardiovascular Nursing.

Dr. Amy Bachyrycz PharmD: will act as preceptor and liaison between UNM College of Pharmacy and Walgreens Pharmacy. Dr. Bachyrycz has extensive experience providing care in the community pharmacy setting.

PharmD students who have an understanding they will participate in this study from the start/end of the study will work under the supervision of Dr. Bachyrycz. The students will be in the clinical rotation of their studies as P4 PharmD students**.**

9.2. Carla R. Kychik MSN, ANP-C will be responsible for medical decisions, diagnoses, and referrals to other providers (e.g. cardiologist) if indicated.

9.3. Describe other resources available to conduct the research: Walgreens store #6587 fills approximately 750 prescriptions per day. The store is located in a densely populated part of Albuquerque, NM in high business/traffic areas. The goal of 50 patients during recruitment is a feasible goal which can be met. The facilities to conduct the research will be in an already established Walgreens Pharmacy that has individual/private space available for education implementation with each participant over the phone.

10. Prior Approvals

10.1 DNP project chair from MSU has approved project proposal, and Dr. Bachyryz's Walgreens supervisor has approved the project.

10.2 Upload the required Departmental Review Form signed by your Department Chair (or authorized designee if the PI is the Department Chair) into Click under "supporting documents."

10.3 N/A; no radiation will be involved in this study.

10.4 N/A: no biological specimens will be involved in this study.

11 Multi-Site Research

11.1 This site will occur as a collaboration between the UNM College of Pharmacy, Walgreens Pharmacy, and a Doctor of Nursing (DNP) student enrolled in the DNP program at Missouri State University (MSU). All research procedures will occur at Walgreens pharmacy.

- All sites will maintain the most current version of the protocol, consent document, and HIPAA authorization.

- All approved IRB protocols will be maintained at each site.
- All modifications will be communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
- All engaged participating sites will safeguard data as required by local information security policies. Data will be stored in a locked filing cabinet at Walgreens Pharmacy Store #6587. The filing cabinet will be locked inside the pharmacy which is secured by an alarm system, and only accessible with those who have the authorized keys/codes. Data will be entered from paper copies and stored on UNM RedCap. Data will be analyzed at UNM. No data will be sent to MSU, other than in final summary form.
- All local site investigators will conduct the study appropriately.
- All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.

11.2 The method to communicate: adverse events, problems, interim results, data/safety monitoring reports, and closure of the study will occur through UNM Redcap.

11.3 N/A; this is not an FDA-regulated trial.

12 Study Procedures

12.1 This study will occur at Walgreens Store #6587 in Albuquerque, NM. Recruitment will occur during standard-of-care follow up phone calls at Walgreens Pharmacy. If a patient would like to participate, the information will be mailed to them with a follow-up phone call to review all the information over the phone with them. Phone calls will be made in a private room in the pharmacy. Dr. Amy Bachyrycz, PharmD will oversee the study procedures at Walgreens Walgreens Store #6587.

12.2 Patients will be screened for eligibility for the study at Walgreens Store #6587, with pharmacists supervising the PharmD students. Screening will be conducted with the Interview Guide included in this IRB submission as "UNM HTN Prescreen for Potential Participants." Eligible potential participants will have consent forms read and given the opportunity to ask questions about the study. Participants may choose to enroll in the study at that time, or given more time to be mailed consent forms at home and decide at another time.
Once the participant consents to participation, the materials will be mailed to the participant, and the participant will complete a pre-survey ("Pre-survey for UNM HTN Study") and pre-test ("Pre-test for UNM HTN Study") on blood pressure management. Participants will be provided a one-page education with supplemental visual aids on blood pressure management with education provided by PharmD students ("My Planned Behavior for Managing My Blood Pressure"). Participants will be provided a list of suggested apps and websites ("Evidence-

based Websites and Apps for Blood Pressure Management") that they may use if they have a smartphone and/or internet access.
After an initial teaching phone call performed by a PharmD student, a follow-up phone call will be conducted at week 4 and 8 of the participant's enrollment. During each phone call, study personnel will use a telephone script titled "Phone Call Script for My Planned Behavior for Managing My Blood Pressure Participants" to discuss blood pressure goals, behavioral changes, and principles of blood pressure management.
At week 8, participants will either answer their questions over the phone or be reminded to complete a post-test ("Post-test for UNM HTN Study") and post-survey ("Post-survey for UNM HTN Study") and mail in using their SASE.

12.3 The information will be collected prospectively and information will be collected at the onset of enrollment, during an initial teaching phone call, during phone calls at week 4, and 8, and from mailed in pre/post-test; pre/post surveys.

12.4 Initial study activities will occur from the Walgreens Store #6587 in Albuquerque, NM by phone calls: recruitment, enrollment, and initial education. The rest of the information will be gathered by follow-up phone calls at 4 and 8 week intervals, and mail-outs. The phone calls will be made from the Walgreens Pharmacy clinic in a room where the investigator has privacy for the phone calls to speak with the participant.

12.5 Describe, in chronological order, all research procedures and interventions being performed and when they are performed. Include:

- Recruitment: Walgreens Store #6587 by phone
- Screening interview: Walgreens Store #6587 by phone
- Verbal consent and enrollment: Walgreens Store #6587 by phone
- One-page educational intervention ("My Planned Behavior for Managing My Blood Pressure (One Page Handout)") with supplemental visual aids ("DASH diet," "AHA Healthy for Good," and "AHA Blood Pressure Management") will be sent to the mailing address given by the participant with a self-addressed stamp envelope in order to return pre/post-test and pre/post-survey.
- One-page educational intervention with supplemental visual aids: from Walgreens Store #6587 via mail. Education on blood pressure management will be provided to the participant by PharmD students via a phone call after enrollment once patient receives items in the mail. ("Phone call Script for My Planned Behavior for Managing My Blood Pressure Participants").
- Follow-up phone calls at 4 and 8 week intervals: Phone calls will be made to the phone number provided by the participant. Phone calls will be made from private rooms at Walgreens Store #6587. Study personnel will use a phone script ("Phone call Script for My Planned Behavior for Managing My Blood

Pressure Participants") to discuss blood pressure goals, behavioral changes, and principles of blood pressure management.

- Post-test on blood pressure management ("Post-test for UNM HTN Study"): Walgreens Store #6587. The purpose of this test is to determine the participant's knowledge of blood pressure management after the educational intervention. The patient may return the completed test by mail, or answer the questions over the phone if they are unable to mail their responses.
- Post-survey ("Post-survey for UNM HTN Study"): Walgreens Store #6587. The purpose of this survey is to gauge the participant's perspectives on engaging in behavioral changes after the educational intervention. The patient may return the completed test by mail, or answer the questions over the phone if they are unable to mail their responses.

13 Data Analysis

13.1 Descriptive statistics will be used with demographic information, and paired t-tests will be used for the pre/posttest and pre/post surveys. The UNM Statistics Department will assist with statistical analysis.

13.2 Power analysis completed for the paired t-tests to detect difference in pre/post tests and surveys using: one tail, moderate effect size of 0.5, alpha probability of error of 0.05, and power standard of .95 resulted in n=45 (GPower, 2019).

14 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A. This study poses minimal risk to the patient as it utilizes only non-invasive screening interventions (education; surveys; follow-up phone calls).

15 Withdrawal of Subjects

15.1 A patient may be withdrawn from the study should they no longer meet inclusion criteria (for example, if they become pregnant during the study). The patient may also be withdrawn if they are not following the study protocol as agreed upon at the onset of the study. Should the patient no longer be able to be contacted after three phone call attempts, they will be withdrawn from the study. Data obtained up to that point of no contact will be maintained, and used for the study analysis.

15.2 The completion of this study will be on the final call to gather data & final post-test and post-survey from the participant. If they patient did make a behavior change of taking blood pressure at home, we will inquire at this time. Upon completion of the study, the participant will be encouraged to continue to see their primary care physician or other medical provider for continued blood pressure management.

15.3 This is an education-only intervention, and the patient may choose to immediately withdraw from the study and decline any further education or follow up phone calls. Should the patient choose to withdraw at any time, they will be encouraged to follow-up with their primary care physician or other medical provider for continued blood pressure management.
Should the patient no longer be able to be contacted after three phone call attempts, they will be withdrawn from the study. Data obtained up to that point of no contact will be maintained, and used for the study analysis.
Should there be unexpected circumstances such as pregnancy or hospitalization for a major cardiac event (stroke, myocardial infarction, or heart failure exacerbation), that participant's data will be used up to the time of the event that causes withdraw.

15.4 Collected data for any withdrawn participants will be maintained in accordance with study protocol.

15.5 Participants will be informed in the consent process that they may choose to withdraw from the study at any time for any reason.

16 Data Management/Confidentiality

16.1 N/A Data will be entered and stored on UNM Redcap.

16.2 The research team will have access to stored information about the subjects that will be maintained in a locked filing cabinet inside a pharmacy that is accessible only with keys and/or personal access codes. The research team will have access to the UNM Redcap Database.

16.3 This research will involve the collection of patient's name. The patient's name is needed for review of their medication profile at Walgreens and for making follow-up phone calls. Participants will be assigned an ID code to be placed on all documents. The ID code and the participant's name will not be recorded on the same documents. The only link between ID code and participants' names will be on a master list which will be stored in a locked filing cabinet which will be placed inside a pharmacy accessible only via personal access codes and keys. Information contained on envelopes that patients may mail back to the pharmacy (patient name and address) will be shredded upon receipt.

16.4 This research will involve access to Protected Health Information (PHI), including the patient's medication profile at Walgreens.

16.5 The data is not publicly available.

16.6 The data is not considered sensitive; information collected in this study will relate only to the patient's blood pressure management and their behavior and behavioral changes to manage their blood pressure.

16.7 This study will not utilize a Certificate of Confidentiality.

16.8 Data will be stored in locked filing cabinet inside a pharmacy that is only accessible with keys and/or personal access codes. Data will be entered into UNM Redcap.

16.9 N/A

16.10 Data will not be transferred or transmitted to outside locations or entities. Data will be stored in locked filing cabinet inside a pharmacy that is only accessible with keys and/or personal access codes. Data will be entered into UNM Redcap. No data will be sent to MSU, other than in final summary form. Information contained on envelopes that patients may mail back to the pharmacy (patient name and address) will be shredded upon receipt.

16.11 Collected information will include answers to initial screening questionnaire, patient name, date of birth, gender, ethnicity, phone number, mailing address, pre/post-tests, pre/post-surveys, self-reported blood pressure readings, and self-reported medication changes. Data collected on hard copy forms will be input into UNM RedCap. Data will be recorded onto a hard copy forms for initial screenings, pre/post-tests, pre/post surveys, consent/HIPAA forms. Data will be stored for 6 years after initial consent. Only study personnel will have access to data.

16.12 N/A

16.13 N/A-Data will not include audio or video recordings

16.14 N/A-Data will not include photographs

16.15 Research records will be maintained for 6 years after initial consent and HIPAA authorization.

16.16 N/A – minors are not included in this study

16.17 HIPAA Requirements: Records will be retained for 6 years after each subject's initial consent.

17 Data and Specimen Banking

Data collected in this study will only be used for the completion of this project and not used in any future projects.
No specimens will be collected/banked in this study.

18 Risks to Subjects

18.1 This study poses minimal risk to the participants, and uses only non-invasive interventions. The intervention consists of education intended to assist the patient with behavioral changes that may result in improved blood pressure management. Participants may experience some discomfort when answering pre-test/survey or post-test/survey questions. Participants may experience a loss of confidentiality

and/or privacy.

19 Potential Benefits to Subjects

19.1 The potential benefit for the participant is to achieve a better understanding of positive behavior changes to continue management of their blood pressure after study ends.

20 Recruitment Methods

20.1 Participants will be recruited from Walgreens Store #6587 by phone call. Participants will be recruited through the end of September 2020.

20.2 Potential participants are those who pick up their medications from the pharmacy, and during standard-of-care follow-up phone calls from Walgreens Pharmacy. The participants' medication profile will be reviewed and an initial interview will be conducted to determine if they meet study criteria.

21 Provisions to Protect the Privacy Interests of Subjects

21.1 Recruitment: Participants will be screened for interest by phone call during a standard-of-care follow-up phone call from Walgreens Pharmacy. The person making the phone call to collect the data will be in a secure area with no other/outside people able to hear the conversation. The person making the call will ask the participant at the onset of the call if this is a good time for them to talk so the receiver of the call also has their own privacy.

21.2 All follow up will be conducted by phone calls or mail-in information. The person making the phone call to collect the data will be in a secure area with no other/outside people able to hear the conversation. The person making the call will ask the participant at the onset of the call if this is a good time for them to talk so the receiver of the call also has their own privacy.

22 Economic Burden to Subjects

22.1 There are no costs associated to the participant in this study.

23 Compensation

23.1 There is no compensation for participants. There will be an incentive of one complimentary pill box, valued at approximately $5, for each participant.

24 Compensation for Research-Related Injury

24.1 There is no foreseeable injury as this study utilizes only non-invasive procedures and interventions.

25 Consent Process

25.1 Participants will be verbally consented prior to participating in the study.

25.1.1 Consent will be obtained by Dr. Amy Bachyrycz and the PharmD students (Chas Montoya, Jesse Robinson, Kyle Ortiz, Ryan Ault) at the onset of the project verbally with each participant using the attached consent document generated from HRPO template version December 2, 2019. Study personnel participating in recruitment and consenting have completed CITI training. The students will be trained on the consent process, to include provisions for ensuring patient privacy, verbally reviewing the consent form and answering the participant questions. They will be using the teach-back method to ensure participant understanding.

25.1.2 The verbal consent process will take place over the phone from a private area at Walgreens Pharmacy.

25.1.3 The only incentive offered to the patients in this study is one pill box, valued at approximately $5. No additional offers of incentives will be made to induce participation.

25.1.4 Participants will be verbally consented. Potential participants who wish to consider the consent for a longer may enroll at a later time during the enrollment period.

25.1.5 Participants will be asked to verbally consent to their continued participation in the study at each follow-up phone call and their final visit. If patient does not consent to their continued participation, their participation in the study will be ended and no further data collected.

25.1.6 Research personnel will verbally review the consent form with the participant to gauge the participant's understanding of the study procedures. Participants will have the opportunity to ask additional questions during the consent process.

25.1.7 The teach-back method will be utilized to ensure participant understanding of the consent (e.g. "We've talked about a lot of information today. If you were to tell a friend about this study, what would you tell them?")

Subjects not fluent in English – N/A; this study will only include English-speaking, reading, and writing individuals.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative – N/A; this study will only include adults able to consent for themselves.

Subjects who are not yet adults (infants, children, teenagers) – N/A; this study will only include adults.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered) – We are requesting a waiver of obtaining a signature from subjects on a consent form to document consent. We are requesting to obtain verbal consent only, as this study will not be conducted face-to-face.

26. Documentation of Consent

26.1 Consent will be obtained using the script and consent document generated from HRPO template version December 2, 2019, included in this submission.

26.2 N/A

26.3 N/A

27 Study Test Results/Incidental Findings

27.1 Individual Results will be from each participant's responses to their pre/post-test and pre/post survey, and responses to the phone script used during initial, week 4, and week 8 phone calls.

27.2 Incidental Findings: We do not anticipate any incidental findings in this study. Participants have already been diagnosed with hypertension as per the inclusion criteria of the study.

28. Sharing Study Progress or Results with Subjects

28.1 The progress of the study will be verbally shared with the participant during each follow-up phone call and during the final study visit upon the participant's request.

28.2 The results of the study will be shared with the public in the form of plain language summary of research findings when ready for publication. Participants may request a summary of the research findings at the conclusion of the study.

29 Inclusion of Vulnerable Populations

This study will not include vulnerable populations.

30 Community-Based Participatory Research - N/A

31 Research Involving American Indian/Native Populations - N/A

32 Transnational Research - N/A

33 Drugs or Devices

33.1 Drugs: The study procedures do not involve drugs. Patients in this study may take medications as part of their blood pressure treatment; however, this study does not involve any intervention for prescribing or providing medications to the participant. Patients will only receive education aimed at behavioral changes that may improve their blood pressure management. While patients may receive their medications from Walgreens as part of their usual course of care, study personnel will not prescribe, modify, or provide patient medications as part of the study intervention. The patient will be encouraged to continue their care with their primary care physician or other medical provider for management of their blood pressure and medications.
Devices: The study is not intended to study the safety of effectiveness any specific device.

33.2 N/A

33.3 N/A

33.4 N/A

33.5 N/A

34 Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of <u>de-identified data</u>**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**

3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

35 CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36 Partial Waiver of Consent for Screening/Recruitment - N/A

37. Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

☐ Yes. Describe:

☒ No – The potential participant's Walgreens pharmacy medication profile will be accessed to determine eligibility, but information from this profile will not be recorded.

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☒ True

☐ False

38 Waiver of Documentation of Consent

Complete this checklist if you intend to obtain consent verbally but will not be obtaining signatures from subjects on a consent form to document consent. Waivers of documentation of consent are commonly requested when using scripts, information sheets, or email or survey introductions to present the elements of consent instead of using a traditional consent form.

A. Are you requesting a waiver of documentation of consent for some or all subjects?

☒ All

☐ Some. Explain:

B. Provide justification for <u>one</u> of the following:

i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

N/A

ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

This research poses no more than minimal risk to the participant, as it involves educational interventions only. Research procedures will occur only over the phone or via mailed-in materials.

C. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

☐ Yes. Please attach a copy to your submission in Click.

☒ No – The consent form will be reviewed over the phone with the patient; research personnel will document verbal consent. The consent form will be mailed to the patient.

39 Alteration of Consent - N/A
40 Full Waiver of Consent/Parental Permission - N/A
41 Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs) - N/A
42 Full Waiver of HIPAA Authorization (Checklist) - N/A
***43* Other Waiver Types (Checklist) -** N/A

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44 Vulnerable Populations (Checklist) - N/A

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45 Medical Devices (Checklist) - N/A
46 Export Control (Checklist) - N/A
47 Data Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

48 Specimen Transfer/Sharing (Checklist) - N/A

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