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 at least 12 months (potentially up to 18 months if there are any delays during the course of the study). 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

have trouble reaching you. If we contact this person, we will only tell them that you are in a research study at the University of Iowa, not what the study is about.

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. You will be asked to return the cell phone to the research team once your participation in the study has ended. 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.

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

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 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.

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 EXPIRATION DATE: 06/03/22.

_____ _____
(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)