IRB # STUDY00024520

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Collaboration Oriented Approach to Controlling High Blood Pressure (COACH)

PRINCIPAL INVESTIGATORS: Richelle Koopman, MD, MS (573) 882-0598
David Dorr, MD, MS (503) 418-2387

CO-INVESTIGATOR: William Martinez, MD, MSc (615) 322-3000

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a multi-site study with University of Missouri-Columbia (MU), Oregon Health & Sciences University (OHSU) and Vanderbilt University Medical Center (VUMC).

PURPOSE: The purpose of the study is to learn how well the COACH application can help lower blood pressure. We are hoping to find out ways to help people manage high blood pressure.

DURATION: Your participation in the study will consist of three surveys over 6 months and blood pressure monitoring from home. Surveys will last up to 20 minutes each.

PROCEDURES: If you decide to participate, you will be asked to complete surveys now, in 8 weeks and in 6 months. You will also be asked to use the COACH application and to monitor your blood pressure during those 6 months.

RISKS: The main risk is a loss of confidentiality. You may also feel side effects that are common during blood pressure management.

BENEFITS: You may not directly benefit from taking part in this research. The COACH application may help you reduce your blood pressure.

ALTERNATIVES: You may choose not to participate in this study, may receive standard blood pressure treatment or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Study Team if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

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CONTACT INFORMATION:
Email: COACH-OHSU@ohsu.edu
Phone: 833-462-9191

WHO IS PAYING FOR THE STUDY? *Agency for Healthcare Research and Quality (AHRQ)*

WHO IS PROVIDING SUPPORT FOR THE STUDY? *None*

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY? *No*

WHY IS THIS STUDY BEING DONE?
You have been invited to be in this research study because you have high blood pressure and your clinician or care team recommend that you participate in a home blood pressure monitoring program. The purpose of this study is to evaluate the effectiveness of the COACH application to lower blood pressure using evidence-based research and patient participation to maximize effectiveness.

A total of 550 patients will be enrolled into the study. Patients are asked to participate in this study for 6 months. You will be asked to monitor your blood pressure using the COACH application and complete surveys.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?
In addition to your regular blood pressure management regiment, you will use the COACH web-based application to measure your blood pressure regularly. You will be provided a link that directs you to instructions on how to use the COACH application. You will be asked to measure your blood pressure regularly from your home. We will provide you with a blood pressure cuff with Bluetooth connection to use at home and record your results in COACH. You will receive information about your blood pressure readings and may receive additional recommendations. Your health record information including medications and blood pressure will be accessed by COACH.

You will complete surveys at three time points. The surveys will ask questions about how you manage your health and your experience using the COACH application.

Below is a breakdown of study procedures you may expect to complete as a participant in this study:

	Baseline Day 1	Week 8 (2 months)	Week 24 (6 months)
Consent Discussion, Screening questions and Survey #1	X		
Receive information on how to use COACH	X		
Survey #2		X	
Survey #3			X
Study payment for completing survey #3			X
Total time	30-60 minutes	20-25 minutes	20-25 minutes

WILL I RECEIVE RESULTS FROM THE STUDY?
You will not receive results from this study. However, your care team will be notified when your blood pressure is high (>180mmHg/120mmHg) or low (<90mmHg/60mmHg).

If you are interested in staying informed about the progress being made on the development of the application, and continuing to contribute to the development process, we may ask for your permission to contact you again in the future.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. You may also experience some side effects commonly experienced when people manage their blood pressure could include dizziness.

PERMISSION TO USE YOUR PROTECTED HEALTH INFORMATION:
State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will be deidentifying information for data analysis.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, email addresses, medical record number, social security number.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) overseeing the study at the University of Missouri, the Agency for Healthcare Research and Quality, or Office of Human Research Protection (agencies that oversee research). Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

We may continue to use and disclose your information as described above indefinitely to disseminate research findings and results.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the study team.

After you join the study, you can choose to receive all future survey links and reminders by text message. If you choose this option, you are giving us permission to share your phone number with our vendor Twilio Inc. to send you these text messages.

We will limit the content of the text messages to general information such as survey links and reminders to complete your survey. Even so, these messages may contain information that you wish to keep confidential. Text messaging is not encrypted, messages can be intercepted by others, viewed by people who see your phone or sent to the wrong person, and may not be confidential.

If, at any point, you no longer wish to receive text messages from the study team, tell us by sending an email to COACH-OHSU@ohsu.edu or calling this number 1-833-462-9191, and we will stop sending you text messages.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your medical condition. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

If you remain in the study and complete the final survey at 24 weeks (6 months), you will receive a $20 payment via electronic gift card. The gift card will be delivered via email and you will have an option to choose between Amazon, Walmart or Target.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact **COACH-OHSU@ohsu.edu**.

If you are injured or harmed by the study procedures, you will be treated. Any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Richelle Koopman at koopmanr@health.missouri.edu or other members of the study team at COACH-OHSU@ohsu.edu. or call 833-462-9191.

If you have questions about your rights as a research participant, please contact the MU Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

As a participant in this study we will ask you to monitor you blood pressure regularly and record it in the COACH application. We will also ask you to complete surveys at three time points during the study.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the study team if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

COACH Coordinator: COACH-OHSU@ohsu.edu (one email for all 3 sites)

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The information that we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

You may be removed from the study if the investigator or funder stops the study, your primary care provider believes it is not safe for you to continue with the study, or if you meet the exclusion criteria after signing this consent document.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study. We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date