MAYO CLINIC

Name and Clinic Number

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Patient-Provider-Community Health Worker Integrated Care Model: Use of an Innovative Mobile Health Intervention to Improve Hypertension among African-Americans

IRB#: 19-009247

Principal Investigator: LaPrincess Brewer, MD, MPH

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test the feasibility of delivering health education and self-management support to African American patients with uncontrolled high blood pressure. You have been asked to take part in this research because you have uncontrolled blood pressure and are a part of the African American Community.
What's Involved	Study participation involves use of the smartphone application (app called the FAITH! Hypertension App) to provide education on how to improve your blood pressure and to monitor your home blood pressure readings. The program also includes meetings with a Community Health Worker to work with your primary care provider to help

	control your blood pressure (meeting options via online platforms such as Zoom or telephone or at your local clinic will be available based on your preference.
Key Information	The risk of completing surveys is minimal; however, you will be asked questions about personal habits and beliefs about your health. We hope that you will answer all of the questions on the surveys, but you may skip questions that you cannot or do not want to provide an answer. These answers and measurements are confidential—the study staff will not share them with others. Taking part in this research study may lead to charges for visits with your provider associated with participation in the study. As the intervention makes use of a web-based app (rather than an app that is only housed on your mobile device), there is a minimal risk that participants will incur costs related to their own personal smartphone data plan. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** LaPrincess Brewer, M.D. **Phone:** (507) 266-1376 **Study Team Contact:** Allison Schneider **Phone:** (507) 422-5435 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

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

A description of this research study will be available on *https://www.mayo.edu/research/clinical-trials.* This web site will not include information that can identify you. You can search this website at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are an African-American adult within the Minneapolis, Minnesota area community with uncontrolled high blood pressure.

About 70 people will take part in this research study.

Why is this research study being done?

We are looking to refine the FAITH! App, an existing culturally-tailored smartphone application (app) and test its feasibility of delivering health education and self-management support to African-American patients with uncontrolled high blood pressure to try and help improve high blood pressure results in participants.

Information you should know

Who is Funding the Study?

This study is being funded by the National Institute of Health (NIH), Minnesota Department of Health (MDH) and the Center for Disease Control (CDC).

The National Institute of Health (NIH), Minnesota Department of Health (MDH) and the Center for Disease Control (CDC) will pay Mayo Clinic to cover the costs related to running the study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation.

If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

Your participation through use of the FAITH! Hypertension App will last approximately 9 months.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

During your baseline visit, you will meet with a Mayo Clinic study coordinator and a Mayo Clinic Community Health Worker. During this visit you will be trained to utilize the FAITH! Hypertension App on your personal smartphone or study provided tablet. You will have a blood pressure check, your weight measured, and your height measured. You will be asked to complete electronic surveys, complete blood pressure related education modules, and take blood pressure readings over a 10 week period. Additionally the app will allow you to enter other information such as medications.

You will be provided a home Blood Pressure monitoring system linked to the app which will allow you to self-measure and enter your results for clinical tracking. You will be asked to meet with a Community Health Worker approximately once a week either virtually (by online platforms such as Zoom or telephone) or preferred location (such as the North Point clinic) to review your progress with the app and your blood pressure readings. These readings will be sent to your clinic (North Point) so your healthcare provider can review. Any clinical follow up will be at your provider's discretion.

You will have three follow up visits right after you finish your 10 week app program and then approximately 3 months and 6 months later. During this visit the study team will repeat your blood pressure and weight, and you will complete follow-up surveys related to your use of the FAITH! Hypertension App.

Optional end of program focus group meeting:
There will also be an optional focus group meeting (about 2 hours long) after the program is over where you can provide us with more information about the program to talk with us about how you think the program should be changed or improved. About 15 participants will be selected for this optional meeting on a first-come basis.

What are the possible risks or discomforts from being in this research study?

The risk of completing surveys is minimal; however, you will be asked questions about personal habits and beliefs about your health. We hope that you will answer all of the questions on the surveys, but you may skip questions that you cannot or do not want to provide an answer. These answers and measurements are confidential—the study staff will not share them with others.

Taking part in this research study may lead to added costs to you. As the intervention makes use of a web-based app (rather than an app that is only housed on your mobile device), there is a minimal risk that participants will incur costs related to their own personal smartphone data plan. Any appointments with your provider as directed by the study may be billed to you in the same manner as your normal clinical care.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, or Mayo Clinic IRB (Institutional Review Board), may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don’t follow the study procedures,
- if the study has stopped

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

The benefit of the study is that subjects will receive health information from health care professionals on high blood pressure which may help reduce risk for heart disease or future heart disease-related events if subjects already have heart disease.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Use of the FAITH! App
- Use of the Blood Pressure Monitor and recordings

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. You may be charged for visits with your provider associated with participation in the study.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study. However, if you choose to participate, you will be provided with the following incentives:

- A $50 cash card in appreciation of your time and effort at enrollment, $25 at immediate follow-up assessment, $25 at 3-month follow-up assessment and $25 when you finish the whole study (after 6 month follow-up assessment).
- You will also receive a home blood pressure monitor for use throughout the study that you can keep.
- Optional: A $50 cash card in appreciation of your time and effort for participation in the end of program focus group meeting.

Will your information be used for future research?

Data obtained from this study which have been anonymized (= data cannot be connected to you in any way) may be used in future related research and your consent and authorization to participate in this study represents your consent and authorization to the use of your anonymized data in future related research.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

By agreeing to participate in the study, this gives permission to share personal and health information with the Community Health Worker, which includes your age, name, demographics address, phone number, income, medications, and blood pressure results.

We will protect your information by giving you and each person in this study a unique identification number. All data will be kept in secure locations or on password protected computers and only approved research personnel will have access. If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions.

- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.
If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature