**********DO NOT DELETE OR ALTER THIS PAGE**********

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

****

INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**: Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

---------- **IRB OFFICE USE ONLY** ----------

Study ID: HUM00210954 / Amendment ID: Ame00157929

Approval Date: 10/24/2024

Document Finalized: 2/10/2025 3:15 PM

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

A Just-In-Time Adaptive Mobile Application Intervention to Reduce Sodium Intake and Blood Pressure in Hypertensive Patients: LowSalt4Life

Company or agency sponsoring the study:

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institute of Health (NIH)

Principal Investigators:

Brahmajee Nallamothu, MD & Michael Dorsch, PharmD, MS

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for hypertension. This research will use a new smartphone app in a large group of people. We hope to learn if the app can help reduce sodium intake and increase healthy lifestyle behaviors in patients with hypertension.

If you choose to participate in the study, you will be asked to use the study mobile app daily. You will also be asked to take your blood pressure and weigh yourself every two weeks. You will also be asked to complete a set of surveys when you enroll in the study and again at 2 months and 6 months. A study team member will contact you at 2, 4, and 6 months to ask you a few questions.

The study staff will also gather information from your electronic health record. This will include information such as personal information (for example, age, sex), medical history related to your hypertension, vital signs, labs, and medications.

This study involves a process called randomization. This means that whether you receive personalized notifications in addition to the general education content in the app is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable with not being able to choose your randomization group.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include extreme sodium restriction could lead to renal

insufficiency and/or hypotension. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by gaining information on hypertension self-management strategies and how you can improve your blood pressure. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 6 months.

You can decide not to be in this study. Alternatives to joining this study include receiving standard of care from your healthcare provider(s).

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

High dietary sodium intake is linked hypertension (high blood pressure) and cardiovascular events. Research has shown that lower sodium intake reduces both blood pressure and prevents cardiovascular diseases. This research is being done to learn if a smartphone app can help patients with hypertension manage their sodium intake and improve their blood pressure.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adults aged 18 and older who have been diagnosed by a healthcare provider with hypertension and have been taking blood pressure medications for a least 3 months may be eligible to participate.

3.2 How many people are expected to take part in this study?

A total of approximately 425 participants are expected to take part in this study, all from the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you attend at all your scheduled appointments, use the mobile app, and report any adverse reactions you may have during the study.

Your participation in this study will last approximately 6 months. All study activities will take place at home. There will be no need to go to the hospital or clinic for the research study, although you should continue to attend any other scheduled medical visits.

Screening:

The following items will be used to determine if you qualify to take part in this study:

- The study staff will review your medical record to make sure you meet all the study requirements.
- Your current sodium intake is greater than 1,500 mg per day

Before any study-related tasks take place, you will be asked to read, sign and date this consent document. If decide to take part in this study and decide the study is right for you, then the following will happen:

After consenting, you will be asked to complete some surveys and to download the study app. You will be asked to give us your home address. We will use this to send you a blood pressure monitor and a scale. The study staff will train you on how to use the study devices and study app.

This study involves a process called randomization. This means that whether you receive personalized notifications in addition to the general education content in the app is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable with not being able to choose your randomization group.

The study app intervention is called a "just-in-time adaptive intervention." It is just-in-time because the intervention is presented to you at the time when you need it. It is adaptive because it learns about you over time and is personalized to your situation. The intervention uses your mobile phone camera and sensors, including Wi-Fi, Bluetooth, accelerometer, gyroscope, magnetometer, and GPS (location). These are used to determine the right time to give you the help you need.

To participate, all permissions must be accepted during the enrollment process to ensure the app functions properly. We use a company, NumberEight, to analyze the changes in your mobile phone sensors to personalize the interventions. NumberEight does not collect identifiers on users. NumberEight will use a unique identifier to link you in the study app. Study staff will not have access to your exact location. We will only know if you location falls into our 3 general location categories – home, restaurant, or grocery store. We will not know any specifics about your location such as address, restaurant name, or grocery store name.

The study will not pay for cell phone data used by the study app. You will be responsible for paying for the data usage on your phone. It is estimated that the use of the study app, study devices, and surveys will not take more than 5 minutes of your time per day. As such, data usage related with the study activities will be minimal.

Two study devices will be provided to you: a blood pressure and heart rate monitor and a scale. The study devices are being supplied by Withings. To ship the study devices directly to your home, the study staff will need to provide Withings with your first and last name, address, birthdate, email, gender, address, phone number, time zone, height and weight. Withings will also have access to the data from the blood pressure monitor and scale.

If you have any problems with the Withings devices or the LowSalt4Life app, please contact your study coordinator. If you have not set up the study devices within a few days of receiving them, a research staff member may reach out to you to offer help with the set-up process.

Full privacy policies can be accessed via the links below:

NumberEight: https://tinyurl.com/2p8wt2ve

Withings: https://www.withings.com/us/en/legal/privacy-policy

LowSalt4Life app: https://lowsalt4life.com/privacy-policy/

You will have the following study visits and undergo the following procedures:

- At **enrollment,** you will download and create an account for the LowSalt4Life study app.
    - You will be asked to complete several online surveys about your dietary habits.
    - You will complete some of these surveys again at home, via email, at month 2 and month 6. A device with internet capability (for example, smartphone, desktop or laptop computer, or tablet) will be needed to complete these surveys.
- At the **baseline** visit, you will:

- Complete the device set-up process with the coordinator
- Take your blood pressure and weigh yourself using the study-provided devices.

- At **Week 2** you will complete a tech check-in follow-up phone call with the study coordinator.
- **Every 2 weeks** you will:
  - Weigh yourself using the study provided scale. The study is not specifically designed to promote weight gain or weight loss. If you are concerned about any weight gain or loss, please contact your doctor.
  - Take your blood pressure measurement using the study provided blood pressure monitor. The blood pressure monitor does provide feedback based on recommendations from the American Heart Association. The study staff is not monitoring these readings. If your device notifies you of high blood pressure readings, it is strongly recommended you contact your doctor(s) or seek medical attention.
- At **Month 2, Month 4, and Month 6** you will complete a follow-up phone call with the study coordinator. They will ask you about any changes to your medical history during the call.
- We ask that you do not disable or edit notifications for the study applications during the 6-month study period as this will give us inaccurate results.
- If you are in the intervention group, you may be invited to participate in an optional 45–60-minute interview about your experience in the study after you have **completed your 6-month participation**.

4.2 How much of my time will be needed to take part in this study?

Each participant will be in the study for 6 months. Below is a table with the estimated time it will take to complete the study activities for each study visit:

Study Assessment	Screening / Enrollment Visit	Baseline	Week 2	Every 2 weeks	Month 2	Month 4	Month 6
Self-Care Confidence in Low Sodium Diet (Approximately 5 minutes)	✓						
FFQ (Approximately 45 minutes)	✓				✓		✓
Block Sodium Screener (Approximately 5 minutes)	✓				✓		✓
Blood Pressure and Weight (Approximately 15 minutes)		✓	✓	✓			
Device set-up (Approximately 15 minutes)		✓					
Follow-up Phone Call (Approximately 15 minutes)			✓		✓	✓	✓
Approximate time to complete all activities	**55 minutes**	**30 minutes**	**15 minutes**	**15 minutes**	**65 minutes**	**15 minutes**	**65 minutes**

4.3 When will my participation in the study be over?

Your participation will be over after you complete the 6-month follow-up surveys and phone call.

After completion of the 6-month surveys and phone call, you may be invited to participate in a 45–60-minute interview about your experience with the LowSalt4Life app and the just in time adaptive intervention (JITAI). We are seeking this feedback from participants in the intervention group only, and you may not be part of this cohort. To ensure a diverse group, we will take into consideration demographic information (i.e., race, ethnicity, gender, and age) when inviting participants. This interview is voluntary, and you may choose not to participate. Choosing not to interview will not affect the medical care you might receive at your clinic. If you decide to participate, we will ask for your permission to audio record your interview. However, you do not have to agree to be audio recorded to participate in the interview. Your responses will remain confidential and will only be accessible to our study team. At any time during the interview, you may ask that we turn off the audio recorder or decline to answer any question. You will receive an additional $25 for participating in this interview.

In addition to the time above, we will collect information from your medical records for another **3 years** after your participation. Most subjects will complete their part in the study within about **4 years.** The entire study is expected to last about **5 years**.

4.4 What will happen with my information used in this study?

Your collected information may be shared with the National Heart, Lung, and Blood Institute.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Over adherence to the intervention (extreme sodium restriction). Over adherence could result in restricting sodium or food intake too greatly which could lead to renal insufficiency and/or hypotension.

The researchers will try to minimize these risks by:

- Individuals with an estimated sodium intake less than 1,500 mg per day will be excluded from participating.
- The study investigators and Data Safety and Monitoring Board will regularly monitor any adverse events.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, some subjects may benefit by learning about hypertension self-management strategies and possibly lowering your blood pressure. Others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Your participation is completely voluntary. There may be other ways to treat your high blood pressure, including treatment with medications, or other experimental treatments. Your doctor can tell you more about these other treatments, their risks, and their possible benefits. You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether you wish to take part in this research study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. Any data already collected and used in analysis may not be able to be removed from our dataset, but all future data collection will stop. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you decided to stop the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You receive a blood pressure monitor, a scale, and potentially $100 for participating. You will receive $25 for completing the enrollment visit, $25 for completing all Month 2 study activities, and $50 for completing all Month

6 study activities. If only some of the study activities are completed at Month 2 and 6, you will receive a partial payment of $12 for Month 2 and $25 for Month 6.

If you complete the additional exit interview, you will receive an additional $25 for participating.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research information will be stored in a locked cabinet and in a HIPAA-compliant research database. Your research information will not be made a part of your regular medical record.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available at 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information

(PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the

federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Brahmajee Nallamothu, MD, MPH
Mailing Address: 1701 Huron Parkway, Building 100, Room 136, Ann Arbor, MI 48109
Telephone: 734-647-1624

Study Coordinator: Sabah Ganai
Mailing Address: 1701 Huron Parkway, Building 100, Room 237, Ann Arbor MI 48109
Telephone: 734-763-5317
Email: lowsalt4life@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received a signed and dated copy of the following:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether to allow future use of my data.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to be Contacted for Participation in Future Research

The study team may wish to keep your contact information to invite you to participate in future research projects that may be similar to or completely different from this research project. I understand that it is my choice whether I allow the study team to contact me to be in future research projects.

_____ Yes, I agree for the study team to contact me for future research projects.

_____ No, I do not agree for the study team to contact me for future research projects.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee
I have provided this participant with information about this study that I believe to be accurate and complete. The participant indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____