PARTICIPANT INFORMATION AND INFORMED CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Aging / "A multifaceted adaptive mobile application to promote self-management and improve outcomes in heart failure: ManageHF"**
Protocol Number:	**Pro00046349**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION
You are invited to take part in a research study. This research is studying two smartphone interventions as a possible way to improve health outcomes for heart failure participants. The National Institute on Aging is sponsoring this research study.

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. Taking part in this study is completely voluntary. You may leave the study at any 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, this study involves a daily commitment for 12 weeks. In your decision to participate in this study, consider all of these matters carefully.

This research is studying two new smartphone interventions in a large group of people. We hope to learn if they can increase healthy lifestyle behaviors after participants are discharged from the hospital following treatment of heart failure. Researchers want to learn if the interventions can prevent hospital readmissions and improve quality of life in participants with heart failure.

If you choose to participate in the study, you will be asked to use the study mobile app daily. This involves completing a brief survey. You will also be asked to wear a smartwatch that

measures your steps and heart rate, take your blood pressure, and weigh yourself every day. You will also be asked to complete a set of surveys when you enroll in the study and again at 6 weeks and 12 weeks.

The study staff will also gather information related to your heart failure diagnosis from your electronic health record. This will include information such as personal information (for example, age, sex), history of heart disease and other medical problems, hospital admissions and emergency room visits.

This study involves a process called randomization. This means that you or the researcher do not choose the number of smartphone interventions you receive in the study. The study design divides study participants into separate groups, based on chance (like the flip of a coin). If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may influence whether you decide to join the study. For this study, some of these risks may include no improvement of your current heart failure or not eating enough salt, which could result in new health problems. Information that is more detailed will be provided later in this document.

This study may offer some benefit to you now or others in the future by learning about more effective ways to manage heart failure. More information will be provided later in this document.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to join this research study because you have heart failure.

Heart failure is the most common hospital discharge diagnosis among older adults in the United States. Forty percent of patients are readmitted to the hospital within 1 year following their first hospitalization for heart failure. The most common causes of hospital readmission are: 1) not recognizing when heart failure symptoms are getting worse, and 2) trouble following dietary recommendations. Patients usually only get help with their heart failure when they are at a doctor's appointment or in the hospital. The study staff believes patients might do better if they get help managing their heart failure on a day-to-day basis.

The purpose of this research study is to test the usefulness of two smartphone interventions on preventing hospital readmission and improving quality of life in participants with heart failure.

About 500 people will participate in this study.

RESPONSIBILITIES AND EXPECTATIONS DURING THE STUDY

Your participation in this study will last approximately 12 weeks. If you are consented in the hospital, the only in-person study visit will take place while you are still in the admitted. If you are enrolled within 7 days of discharge, the first visit can take place in-person or remotely based on your preference. All other study activities will take place at home. There will be no need to return 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.
- You have a smartphone with a compatible operating system and are willing to download our mobile phone study app.

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:

Study Treatment:

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

The study app has general information for heart failure participants that everyone in the study receives. Extra content, or interventions, for heart failure symptoms and diet will be randomly assigned to participants. You may receive some, all, or none of the additional content. All participants will be asked to complete a brief survey every day in the study app. You will also be asked to take your weight and blood pressure every day. Since this is research, we do not know which intervention is best.

Neither you nor your study doctor will know which part(s) of the study app you are assigned. This is called blinding. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in. In the event of an emergency, the study staff can find out, or break the blind, to see which groups you were assigned to.

Both interventions within the study app are called “just-in-time adaptive interventions.” They are just-in-time because the intervention is presented to you at the time when you need it. They are adaptive because they learn about you over time and are personalized to your situation. Both interventions use 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.

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 10-15 minutes of your time per day. Please note, the majority of the daily time commitment will be spent taking your blood pressure and weighing yourself. For example, the American Heart Association recommends sitting quietly for 5 minutes before taking your blood pressure. This 5-minute waiting period is included in the daily time estimate. Taking your blood pressure and weighing yourself are routine, standard of care tasks your healthcare provider will ask you to perform regardless of your study participation. The main difference is you will use the study-provided scale and blood pressure cuff to perform these tasks. The daily survey will take approximately 1-2 minutes to complete. As such, smartphone data usage related with the study activities will be minimal.

Three study devices will be shipped to you: a blood pressure monitor, a smartwatch that measures your steps and heart rate, and a scale. The study devices are being supplied by Withings. In order to ship the study devices directly to your home, the study staff will need to provide Withings and the University of Michigan with your name, address, and email address. Withings will also have access to the data from the blood pressure monitor, scale, and smartwatch.

The scale that you receive for this study will be based on your medical history. Both scales are smart scales meaning they connect with your phone. The Body scale is a standard digital scale that will only measure and track your weight. The Body+ scale measures your weight and measures your entire body composition. Body composition is a measure of body fat, water percentage, muscle mass and bone mass.

Scales that measure body fat such as the Body+ scale are NOT recommended for people with pacemakers. If you have a pacemaker, you will get the Body scale since it does not pose a risk to those with pacemakers. If you get a pacemaker placed during your study participation, the body composition feature can be turned off on the Body+ scale. The Body+ instruction manual has information on how to turn this off. You can also contact the study staff at University of Michigan for help with turning off the body composition feature.

The study staff at the University of Michigan is providing tech support for the Withings study devices and ManageHF study app. If you have any problems with your Withings study devices or the ManageHF study app, you can contact the tech support team at (734) 408-4581. If you

have not set up the Withings study devices within a few days of being enrolled, the University of Michigan tech support team will reach out to you to offer help with the set-up process.

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

- You will be asked to complete a short test to measure your thinking ability.
- You will be asked to complete several online surveys about your heart failure symptoms, dietary habits, and mental health. You will complete some of the heart failure symptoms and dietary habits surveys again at home, via email and text message, at week 6 and week 12. A device with internet capability (for example, desktop or laptop computer, tablet) will be needed to complete these surveys.
- After consent, you will download and create accounts for the Withings and ManageHF study apps.
- For the next 12 weeks you will perform activities every day. This includes:
    - Completing a short survey every day in the ManageHF mobile study app.
    - Wearing a smartwatch on your wrist continuously throughout the day and night.
    - Weighing yourself every day using the study provided scale.
    - Taking your blood pressure measurement every day 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. It is your responsibility to contact your doctor(s) or seek medical attention for high readings.
- We ask that you do not disable or edit notifications for the study applications during the 12-week study period as this will give us inaccurate results.

Below is a table with the estimated time it will take to complete the surveys for each study visit:

Study Assessment	**Screening/ Baseline Visit**	**6-Week Visit**	**12-Week Visit**
SCHFI (Self-Care in Heart Failure Index, approximately 5 minutes)	✓		
High 5 alternatives (Approximately 10 minutes)	✓		
MMSE (Mini-Mental State Examination, approximately 10 minutes)	✓		
HADS (Hospital Anxiety and Depression Scale, approximately 5 minutes)	✓		
FFQ (Block Food Frequency Questionnaire, approximately 45 minutes)	✓	✓	✓
Self-MNA (Self Mini Nutritional Assessment, approximately 5 minutes)	✓		✓
NYHA (New York Heart Association, less than 2 minutes)	✓	✓	✓
MLHFQ (Minnesota Living with Heart Failure Questionnaire, less than 10 minutes)	✓	✓	✓

Block Sodium Screener (Approximately 5 minutes)	✓	✓	✓
Follow-up Phone Call (Approximately 15 minutes)		✓	✓
App Summary Survey (Approximately 5 minutes)			✓
Approximate time to complete all activities	97 minutes	77 minutes	87 minutes

After Study Treatment:
Because this is a research study, the smartphone study app will be available to you only during this study and not after the study is over. To thank you for participating, you will keep the blood pressure monitor, scale, and smartwatch. These items do not need to be returned to the study staff.

Your direct participation in the study will be over after 12 weeks. However, the study staff may review your medical records for up to 5 years to study long-term health outcomes.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

For the mobile phone study applications:
Uncommon (less than 1%)

- If you are randomized to the dietary intervention group, you may receive advice on sodium intake. Lowering sodium intake too much can lead to kidney problems or low blood pressure. The risk is small, but important in the clinical trial.
- Programming problems with the interventions: There is a small risk the algorithm for either intervention could be incorrect. This could cause harm, or it could send the wrong information via a push notification. The risk is small, but important in the clinical trial.
- Risk of Loss of Confidentiality: Information obtained during assessments is confidential and used solely for research purposes. While every effort is made to maintain confidentiality and to protect Patient Health Information (PHI), there always exists a small possibility that some information could be compromised.

RISKS OF STUDY PROCEDURES

- Surveys: The surveys used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.
- Body+ Scale: The Body+ scale not only measures your weight, but it also measures your entire body composition. Body composition is a measurement of body fat, water percentage, muscle mass and bone mass. Scales that measure body fat such as the Body+ scale, are NOT recommended for people with pacemakers or defibrillators. If you have one of these devices, you will get the Body scale since it does not pose a risk to those with pacemakers or defibrillators.
- BPM Connect (blood pressure cuff): The BPM Connect has received FDA clearance and is available for the public to purchase. During the FDA clearance process, the BPM Connect passed general electromagnetic testing meaning it does not cause interference with nearby electric devices (e.g. pacemakers). However, the manufacturer has not conducted additional tests to specifically examine its compatibility with pacemakers and

defibrillators. There may or may not be a risk associated with using the BPM Connect if you have one of these devices.

_____ (initials) Yes, I would like to receive and use the BPM Connect for this research study.

_____ (initials) No, I would not like to receive and use the BPM Connect for this research study.

- You will be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.
- As part of this research study, you will have to download the Withings and ManageHF study apps onto your personal smartphone. In order to use the apps, you will be asked to agree to the Privacy Policy and Terms. If you decide that you do not want to agree, then you should decide not to participate in the study. While using the apps, data about you including email address, first and last name, phone number, address and internet usage data will be collected and transmitted to the researchers and to people outside of the research study. A complete description of this data collection and sharing is found in the Privacy Policy. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information. The Privacy Policy provides instructions on how to request deletion of your personal data if you decide to do that in the future.

UNFORESEEN RISKS

Since the study intervention is investigational, there may be other risks that are unknown.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes only. The alternative is to not participate in this study. You will receive the same education from your physician about managing your heart failure regardless of your participation in this study.

NEW FINDINGS

Research results that are clinically relevant, including individual research results, **will not be given to you by the study staff.** However, you can view your own data through Withings at any time. You may choose to share this information with your healthcare providers.

While research results will not be shared, any new important information that is discovered during the study indicating an increased risk for participating will be provided to you. You may be asked to re-sign and date the consent form to indicate that you are still willing to participate.

BENEFITS

You may or may not receive any personal benefit from participating in this study. However, others may benefit from the knowledge gained from this study.

COMPENSATION FOR PARTICIPATION

You will receive up to $200 for participating in the study.
You will receive $50 for completing the enrollment visit, $50 for completing all Week 6 study activities, and $100 for completing all Week 12 study activities. A check will be sent to your home address after your Week 12 visit.

Checks are processed by the University of Michigan. For IRS reporting purposes, your social security number will be shared with the University of Michigan. If your compensation from the University of Michigan equals or exceeds $600 in a calendar year, you will receive a Form 1099. This form is used to report income on your personal taxes. Forms 1099s are sent out in January for the previous calendar year.

The study devices (blood pressure monitor, scale, and smartwatch) are yours to keep at the end of the study and are valued at over $400.

CONFIDENTIALITY

Study staff will protect your personal information closely so no one will be able to connect your responses and any other information that identifies you. Federal or state laws may require us to show information to university or government officials, the U.S. Food and Drug Administration (or sponsors), who are responsible for monitoring the safety of this study. Directly identifying information (for example, names, addresses) will be protected and maintained under controlled conditions. This means that absolute confidentiality cannot be guaranteed. You will not be identified in any publication from this study.

A Certificate of Confidentiality from the National Institute of Health covers this research. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

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.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human participants in federally funded studies. You or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

COSTS

There will be no charge to you for your participation in this study. The smartphone study app and self-monitoring study devices will be provided at no charge to you or your insurance company. You will be responsible for paying for the data usage on your phone.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information collected during this study. It **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent. Other investigators will be certified to handle sensitive information and will obtain human subjects approval based on their study design.

WHOM TO CONTACT ABOUT THIS STUDY

If you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00046349.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Email Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the National Institute on Aging.
- Representatives of the University of Michigan.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the smartphone study app works and is safe.
- To compare the smartphone study app to other treatments.
- For other research activities related to the smartphone.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

CONSENT TO BE CONTACTED FOR OTHER RESEARCH PROJECTS IN THE FUTURE

You are also being asked if you are willing to provide your name and contact information to participate in potential future research studies. If you consent to this section, you will be added to a list of volunteers with heart failure who are willing to be contacted to participate in future research studies. Your name and contact information will be kept in a secure, HIPAA compliant database at the University of Michigan.

Being on this list is completely voluntary. If you decide not to be contacted for future research, your decision will have no impact on your ability to participate in the main study. It will have no impact on any other benefits to which you would otherwise be entitled. If you wish to change your mind in the future and withdraw your consent to be contacted, you may do that at any time.

Please indicate your preference below:

❒**YES** _____ **(initials)** I agree to be contacted for future research studies as described above.

❒**NO** _____ **(initials)** I do not agree to be contacted for future research studies as described above.

If you checked "YES" above, please provide the following information:

PRINT FULL NAME:_____
PHONE NUMBER 1:_____
PHONE NUMBER 2:_____
EMAIL ADDRESS:_____@_____

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose not to participate or you may withdraw from the study for any reason at any time. Your decision will not cost you any penalty or loss of benefits to which you are otherwise entitled and it will not affect your future medical care. If you choose to withdraw from the study, or you decide at any time you would like us to stop following your medical record, please let the PI know in writing as soon as possible. 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.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study tests for your safety.

CONSENT TO PARTICIPATE IN RESEARCH STUDY

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date