Informed Consent Form

Symptom Care at Home-Heart Failure: Developing and Piloting a Symptom Monitoring and Self-Management Coaching System for Patients with Heart Failure

IRB Approval Date: December 16, 2025

NCT04347759

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 50 people who are being studied, at Emory.

Why is this study being done?

This study is being done to answer the question: Is electronic daily symptom monitoring from home effective for heart failure patients either after discharge from the hospital or after your clinic visit. You are being asked to be in this research study because you have heart failure.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 30 days either after hospital discharge or after clinic visit. The researchers will ask you to do the following: To use the symptom monitoring system over 30 days, and to fill out the survey after signing on the consent form and after using the system over 30 days. All of the procedures will be paid for by the study. After signing this form, the research team will use the randomly premade group assignment (either group A or group B), similar to flipping a coin. Each group will use the same electronic daily symptom monitoring system for 30 days but one group will also receive real-time self-management coaching. The research team will provide instructions about the study based on which group you are in. We will also call you weekly to ask about recent ED visits and/or rehospitalization, and healthcare provider contact.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

What are the risks or discomforts you should know about before deciding?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. You may feel discomfort when you receive text messages or phone calls from our research team to remind you to use the system. There is also the risk of loss of privacy and a breach of confidentiality.

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends. The research team will explain the study to you.

Emory University
Consent to be a Research Subject

Title: Symptom Care at Home-Heart Failure: Developing and Piloting a Symptom Monitoring and Self-Management Coaching System for Patients with Heart Failure

IRB #: 00007523

Principal Investigator: Youjeong Kang

Funding Source: National Institutes of Health (7K23HL148545)

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to evaluate an electronic daily symptom monitoring system. You will use the system to monitor your symptoms at home over 30 days either after leaving the hospital or after visiting your clinic.

What will you be asked to do?
There are 2 groups of subjects enrolled in this study. The group you are assigned to will be randomly decided based on a premade group assignment (either group A or group B). This process is similar to flipping a coin. Both groups will use the same symptom monitoring system; however, one group will also receive real-time self-management coaching.

You will be asked to use the symptom monitoring system using 1 of 3 ways: phone, mobile app, or website for 30 days after leaving the hospital. If you prefer using the phone, we will provide a toll-free number for you to call and a password to log into the system. If you want to use the mobile app, we will provide instructions on how to download the mobile app. If you want to use the website, we will provide a screenshot of the website with instructions for access. We will provide a copy of the participant manual before leaving the hospital that includes instructions on how to report your symptoms over 30 days at home. This system does not substitute seeking medical advice directly from health care professionals.

On the first day, in addition to reporting your symptoms, you will fill out the form called the Self-Care of Heart Failure Index asking about how you manage your symptoms. On the last day, in addition to reporting symptoms, you will fill out the form called the Self-Care of Heart Failure Index and questions asking about the system that you used. There are no right or wrong answers to our questions. If you miss using the system more than 3 days in a row, we will call you to check-in. You can choose not to participate at any time. Please feel free not to answer a question if you do not want to. If you feel worsening symptoms, please contact your healthcare provider immediately. You will be asked to report your symptoms to the symptom monitoring system for 30 days.

While you are using the system over 30 days, we may need to gather clinical information from your medical records. If we gather your information, we will use a study number to identify you, not your name or initials. We will destroy any information that includes identifiable information. The information you share with us is confidential. We will not share it with any clinicians. You will not lose any benefits or advantages if you choose not to participate. All papers we write and presentations of the results from this study will only contain the results from data analysis.

Who owns your study data?

If you join this study, your symptom monitoring data and electronic health records data will be obtained and will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. We may also need to disclose information if required by law.

If we share your identifying information with groups outside of the Emory, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.
If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, this will in no way impact your ability to receive health care services at the Emory. If you leave the study, the data that were already collected will still be used for this study.

What are the possible risks and discomforts?

The most likely risks to you of take part in this study are stress and inconvenience. You may feel stress reporting your symptoms every day over 30 days at home. There may be loss of privacy and breach of confidentiality.

Will you benefit from the study?

There is no direct benefit to you from this study.

Will you be paid for your time and effort?

You will be compensated for being in this study. We will provide modest compensation for you by providing:

- $10 for completing baseline questionnaire,
- $1 for each daily symptom report completed,
- $10 for completing the end-of-study interview.

You will potentially get $50 total in gift card, if you complete all study visits.

Emory may be required to report your payment(s) to the IRS depending on how much you receive in a year. You must give the researchers a valid Social Security number or Taxpayer Identification Number for IRS reporting purposes. If you do not, your amount may be reduced because taxes are taken out. Please talk to our team for more details.

What are your other options?

If you choose not to join this study, you can get care outside of this study [Home healthcare services]. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may still be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation

Storing and Sharing your Information

The system is from the University of Utah and Accuretta that developed the system and collect your phone number, your e-mail and your symptom data. Then, we will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you. Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data. We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study. Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:
- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
- To conduct this research study
- To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
- To provide study-related treatment and facilitate payment for such treatment
- To conduct healthcare operations
- To ensure compliance with state and federal regulations and provide oversight of the study
- To determine your health, vital status or contact information should you be unreachable during the study
- For the administration and payment of any costs relating to subject injury from the study including reporting payment information to Medicare/Medicaid where applicable

Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use IIHI is Required to Participate:
By signing this form, you give us permission to use and disclose your IIHI for this research study.

People Who will Use/Disclose Your IIHI:

- The Principal Investigator and the research staff
- The funder of the research, its agents, study monitors and contractors including laboratories if applicable
- Institutional Review Boards (people who provide ethical review of research)
- Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research
- Other researchers and centers that are a part of this study
- Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections, Food and Drug Administration)

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, funder, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, or other questions or concerns about the research or your part in it, contact Youjeong Kang at [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date** **Time**