Informed Consent Form

Title: Integrating Cost Into Shared Decision-Making for Heart Failure With Reduced Ejection Fraction

NCT Number: NCT04793880

IRB Approval Date: September 20, 2021

[Site Name]
Oral Consent and HIPAA Authorization Script/Information Sheet
For a Research Study

Study Title: **Integrating Cost into Shared Decision-Making for Heart Failure with Reduced Ejection Fraction**
IRB #: 00002215
Principal Investigator:
Funding Source: **AHRQ Health Services Research**

Introduction and Study Overview

Thank you for your interest in our research study. We would like to tell you everything you need to think about before you decide whether or not to join 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.

The purpose of this study is to learn more about how patients and doctors communicate about medications and to identify ways to improve communication. The study is funded by the Agency for Healthcare Research and Quality. This study will take place during one regularly scheduled doctor's visit and there is also one 15 minute phone call a few weeks later.

Your doctor has agreed to participate in this study and is willing to have his or her patients included in order to learn more about how doctors and patients communicate about heart failure medicines. If you join, the study involves recording your doctor's visit and asking you some follow-up questions about that visit.

Your doctor's visit will not be changed because of the recording. We will give you a medication checklist to go over with your doctor if you want, and we will set up the recording. We will call you to do a follow-up survey about 2 weeks after your visit. That survey will last about 15 minutes, will be recorded, and we will send you a $25 gift card for completing it. We will also review your chart to see what medications you are taking within the months after your visit, and we will check what medications your insurance company covers.

If you become uncomfortable, you can stop the audio recording of your visit at any time. If you decide to stop the recording, your care will not be impacted at all. The telephone interview does not involve sensitive questions. You do not have to do it, and you can refuse to answer any questions you do not want to answer.

All information that we record (including recordings and health information) will be stored using a special study ID assigned to you, not your name. We will store all information on password-protected computer systems. The code linking your study ID to your name will be in a separate file and destroyed after the study.

Being in this study may not benefit you directly; it is designed to help us to learn more about doctor-patient communication about heart failure medicine. You may find the medication checklist to be helpful.

[Site Name] will keep your information private and follow all research regulations. Your name will be removed from recordings and replaced with a code that will be used to label study records in place of your name. Nothing you say during the visit or survey will be told to [Site Name] doctors, employees, or researchers in a way that could identify you. Your answers to survey questions will not be given to your doctor.

We will partner with a company called TailorMed to find out what medications your insurance covers. They will protect your health information using standard privacy protections and will not release your information.

The only foreseeable risk related to this research is breach of confidentiality.

This study is not intended to benefit you directly, but we hope this research will benefit people in the future.

Your privacy is very important to us. There is a law that protects your health information kept by your medical provider; this law is called HIPAA. Your health information that identifies you is your "individual identifiable health information" (IIHI).
The IIHI for this study includes your name, birthdate, medical record number, insurance provider, and diagnosis. To protect your IIHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). If you join the study, the following persons or groups may use and /or disclose your IIHI for this study:

- The Principal Investigator and the research staff
- AHRQ who funds this Research, and TailorMed
- Emory University and [relying institution] offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing
- Other researchers and centers that are a part of this study.
- Any government agencies who regulate the research including the Office of Human Subjects Research Protections (OHRP).

We will disclose your IIHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.

You may revoke your authorization at any time by contacting the Principal Investigator, [Local PI Name]. If identifiers (like your name, address, and telephone number) are removed from your IIHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

If we share your IIHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your IIHI to others without your authorization. Let me know if you have questions about this. If you do not give your authorization, you may still receive non-research related treatment.

Your authorization will not expire because your IIHI will need to be kept indefinitely for research purposes.

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at [Site Name] or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Contact Information

If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

[Local PI]

If you have questions about your rights at research participant, complaints about the research or an issue you rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or toll-free at 877-503-9797 or by email at irb@emory.edu.

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

_____

Name of Person Conducting Informed Consent Discussion