Informed Consent Forms
Caregiver and Patient

Protocol Title: Improving Self-Care of Heart Failure Caregivers
NCT 03988621

Document Date: (IRB Approved: 13-MAY-2022)

UNIVERSITY *of* PENNSYLVANIA
SCHOOL *of* NURSING

Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 16-May-2022
TO: Barbara J Riegel
CC: Matus, Austin
Thomas, Gladys L.

RE:
IRB PROTOCOL#: 830235
PROTOCOL TITLE: Improving Self-Care of Informal Caregivers of Adults with Heart Failure

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #8

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Riegel,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 13-May-2022.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:
-HSERA modification submission (confirmation # dgcebjcj) submitted 5/11/2022

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported

to the IRB in accordance with Penn IRB SOP RR 404.

- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form

with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

University of Pennsylvania
Informed Consent with HIPPA Authorization Form

Title of the Research Study: Improving Self-Care of Informal Caregivers of Adults with Heart Failure (HF) - Patients

Protocol Number: 830235

Principal Investigator: (name, address, phone and email)
Barbara Riegel, PhD, RN, FAAN, FAHA
Professor, School of Nursing
University of Pennsylvania
215-898-9927
briegel@nursing.upenn.edu

You are being asked to take part in a research study that is registered in ClinicalTrials.gov. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

Consent Summary
This is a study of a support intervention for heart failure caregivers. If your loved one agrees to be in the study, we will ask you to allow us to gather information about you (e.g., type of heart failure, hospitalizations) from the medical record. We will ask you to complete a short survey at enrollment and 12 months later. The risk is an unlikely loss of confidentiality. You will not need to pay for anything but you will receive $25 for participating.

What is the purpose of the study?
People who support adults with heart failure (HF) report significant stress and poor self-care. Self-care are behaviors that people do to keep themselves healthy (e.g. getting enough sleep). The purpose of this study is to test if providing health coaching to these carer may relieve stress and promote their self-care.

Why was I asked to participate in the study?
You are being asked to join this study because you are an adult with heart failure and the person who is providing support to you, your carer is a participant in this study. You will be one of 250 patients in the entire study.

How long will I be in the study?

The study will take place over a 5 year period; however, your participation would be for a period of 12 months.

Where will the study take place?
Your participation may be in-person during a clinic or hospital visit or by telephone. But most participation would be virtual - allowing us to collect information about your health status from the electronic medical record (EMR) system.

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

What will I be asked to do?
If you agree to be in the study, we will collect demographic (e.g. your age) and clinical characteristics (e.g. type and duration of heart failure) from the EMR. We will ask you to complete a short memory survey at the beginning and another survey about quality of life at the beginning and end of the study. We will look at your EMR to obtain information about your medical history, lab tests, medications, therapies, provider visits, hospital records, and events that occur over the next 12 months. We will ask your carer if you have been hospitalized outside of the Penn system. This information will help us determine if improving the self-care of your caregiver has an effect on your health status.

The only identifying information that we will *keep* is your name, date of birth, and medical record number so that we can access your record during the follow-up year. At the end of the 12 month follow-up, we will destroy that identifying information.

What are the risks?
A possible risk is loss of confidentiality. But any document where you can be identified by name will be kept in a locked drawer in a locked file room. These documents will be carefully protected and destroyed 7 years after the study is over.

How will I benefit from the study?
There is no direct benefit to you. We hope the information learned from this study will benefit other people supporting HF patients in the future.

What other choices do I have?
Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your nurse and doctor will not be upset with your decision.

When is the study over? Can I leave the study before it ends?
This study is expected to end after all participants have completed all visits, telephone follow-ups, and all information has been collected. You have the right to drop out of the study at any time during your participation. Withdrawal will not interfere with your present or future care.

How will confidentiality be maintained and my privacy be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Please note, confidentiality may be breached if required by law (e.g. disclosure of intent to harm oneself, others; elder or child abuse). If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Electronic Medical Records and Research Results
The information about you to be used for this study includes information from the EMR. Our research staff will conduct ongoing tracking of your health status from the EMR: medical conditions, lab tests, medications, therapies, provider visits, hospital records, and events that occur over the next year.

As mentioned earlier, an Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

Will I have to pay for anything?
You will not have to pay anything to be in this study.

Will I be paid for being in this study?
You will be compensated $25 on a reloadable prepaid card when you enroll in the study.

What information about me may be collected, used or shared with others?

- We will collect your name, mailing address, telephone numbers, social security number for payment, email address
- Personal history (education, marital status, date of birth, gender)
- Information about you from the EMR over the next year, including use of healthcare services and doctor visits at Penn and other institutions, type and duration of heart failure, medical history, hospitalizations, lab tests, and therapies.
- Medical record number
- Your survey responses are not clinically relevant so we will not return this information to you. We will share a summary of our major results with you as soon as the study concludes.
- Your authorization for use of your personal health information for this specific study does not expire.

Why is my information being used?
Your information is used by the research team to contact you during the study. We will use your personal information to access your medical record. Your history and responses will be used to do the research to see if improving the self-care of your carer has an effect on your health status. Your personal information (name, address, date of birth, social security number) will be used to add money to the reloadable Greenphire ClinCard, a company affiliated with the University of Pennsylvania.

Who may use and share information about me?
The following individuals may use or share your information for this study:

- The investigator for the study and the study team including research staff
- Other authorized personnel such as the Office of Human Research Protections at the University of Pennsylvania
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Once your personal health information is disclosed to others outside the School of Nursing, it may no longer be covered by federal privacy protection regulations.

Future use of data
Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected in this study.

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. If you no longer wish to be in the research study, please leave a message with Dr. Riegel's Research Team at 215-898-5089 and she will remove you from the study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

You will receive a copy of this consent form and this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document, you are permitting the investigators to use and disclose personal health information collected about you for research purposes as described above.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

University of Pennsylvania
Informed Consent with HIPPA Authorization Form

Title of the Research Study: Improving Self-Care of Informal Caregivers of Adults with Heart Failure (HF) - Caregivers

Protocol Number: 830235

Principal Investigator: (name, address, phone and email)
Barbara Riegel, PhD, RN, FAAN, FAHA
Professor, School of Nursing
University of Pennsylvania
215-898-9927
briegel@nursing.upenn.edu

You are being asked to take part in a research study that is registered in ClinicalTrials.gov. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

Consent Summary
We are seeking adults who are supporting loved ones who have heart failure. All caregivers are loaned a Samsung tablet programmed with health information websites. We encourage you to spend at least 30 minutes weekly reviewing the websites. Half of the caregivers are randomly assigned to also receive 6 months of virtual sessions with a health coach. The study lasts 12 months, with data collected by telephone at enrollment, 1, 3, 6, 9, and 12 months. All interactions are virtual. The major risk of participating is fatigue. You do not need to pay anything to be in the study. Caregivers are paid $200 for the 12 months of participation.

What is the purpose of the study?
Supporting another person who is ill is demanding and stressful. People who support adults with heart failure (HF) report significant stress and poor self-care. Self-care are behaviors that people do to keep themselves healthy (e.g. getting enough sleep) The purpose of this study is to test if providing health coaching to these carers may relieve stress and promote self-care.

Why was I asked to participate in the study?
You are being asked to join this study because you support an adult with heart failure. You will be one of 250 carers in the entire study.

IRB Approval: 05-13-2022

How long will I be in the study?
The study will take place over a 5 year period; however, your participation would be for a period of 12 months.

Where will the study take place?
As part of the study, you will receive Health Information (HI) delivered by the Internet. And you will be able to access this information from the tablet devices we provide from your own home or from a location of your choice.

What will I be asked to do?
If you agree to be in the study, you will be asked questions to make sure you qualify for the study (e.g. are you providing care to an adult with heart failure for at least 8 hours per week?). If you qualify for the study, you will be asked to provide some information about yourself (e.g. your age). You will be asked to complete several short surveys asking about your self-care behaviors (e.g. during the past month, have you put off going to the doctor?), medical history, and support behaviors. If it is not convenient for you to complete the surveys at our first meeting, a home visit will be scheduled to complete this process.

After all information has been collected, you will be randomly assigned to one of two (2) groups. You will not be able to choose your group. Selection for the 2 groups is done randomly by the study computer. This means that the group you are placed in is determined by chance – like flipping a coin. After receiving your group selection:

Regardless of the group you are randomly assigned to you will:

- Receive Health Information (HI) delivered by the Internet.

- Receive a tablet device to use for the first 6 months of the study so you can access the internet site providing the HI content. Tablets will be supplied by Caryl Technologies, LLC. In the event that your tablet device is lost or stolen, another one will be provided at no cost to you. You will not require internet service to participate in this study. A data plan will be provided and is included on the tablets. Research staff will provide instruction on how to use the tablet and how to access the HI websites.

- Be encouraged to spend at least 30 minutes weekly using the HI website modules for 6 months. You will receive monthly reminder cards by mail.

- Receive a research diary to aid tracking of health care used and costs you have incurred.

- At 3, 6, 9 and 12th month of your participation, our research staff will call you by telephone to ask you some questions about your self-care, stress, coping, work and health care use.

If you are randomly assigned to the Coaching Group:

- You will also receive 10 health coaching sessions during the first 6 months. These sessions will be provided through the tablets via Secure VidyoConferencing software so that you can see the health coach. Each coaching session is expected to take about one hour. Sessions will be conducted weekly initially and decrease in frequency over time.

For quality and training purpose, sessions will be recorded. Audiotapes of sessions will be transcribed by a HIPAA –compliant company and used for analysis.

- Although internet access will be provided for HI website access and videoconferencing, the tablets will be disabled for personal use of the Internet. Your data will be de-identified to the technology companies and a pseudonym (false name) will be used for tracking purposes.

What are the risks?
You may become tired doing the surveys. If you get tired, you can ask the interviewer for a break, do the surveys at a later time, or stop the survey. Another possible risk is loss of confidentiality. But any document where you can be identified by name will be kept in a locked drawer in a locked file room. These documents will be carefully protected and destroyed 7 years after the study is over. The surveys you complete are only for research and have no clear meaning for health care. Nothing about your study responses will be placed in your medical record or reported to your physician.

How will I benefit from the study?
There is no direct benefit to you and we cannot guarantee that any participant will benefit by participating in this study, although all caregivers will receive health information. We hope the information learned from this study will benefit other people supporting HF patients in the future.

What other choices do I have?
Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future.

When is the study over? Can I leave the study before it ends?
This study is expected to end after all participants have completed all visits, telephone follow-ups, and all information has been collected. You have the right to drop out of the study at any time during your participation. Withdrawal will not interfere with your future care.

How will confidentiality be maintained and my privacy be protected?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Please note, confidentiality may be breached if required by law (e.g. disclosure of intent to harm oneself, others; elder or child abuse). When information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Electronic Medical Records and Research Results
The information about you to be used for this study includes information from the electronic medical record (EMR). The EMR is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

Our research staff will conduct ongoing tracking of you and the HF patient you support from the EMR. This tracking will involve medical conditions, lab tests, medications, therapies, provider visits, hospital records, and events that occur over the next year.

Will I have to pay for anything?
You will not have to pay anything to be in this study.

Will I be paid for being in this study?
You will be compensated a total of $200 for completion for the duration of the study. You will receive a reloadable prepaid card with detailed instructions for how to use, activate, and check your balance.

You will be paid:

- $25 at enrollment
- $25 when you complete the 3-month telephone follow-up
- $25 when you complete the 6-month telephone follow-up
- $25 when you complete the 9-month telephone follow-up
- $100 when you complete the12-month telephone follow-up

What information about me may be collected, used or shared with others?

- We will collect your name, mailing address, telephone numbers (yours and that of a close relative), and email address
- Personal history (education, marital status, date of birth, gender)
- Information about you and the HF patient you support from the EMR over the next year, including use of healthcare services and doctor visits at UPHS over the next year, type and duration of heart failure diagnosis for the HF patient, medical history, hospitalizations, lab tests, and therapies. In cases where healthcare use is not in the UPHS system, if needed we will ask that a release is signed to access it.
- Medical record number
- Your responses to survey questions about your self-care, perceived stress, and coping with your support role. None of this information is clinically relevant so we will not return this information to you. We will share a summary of our major results with you as soon as the study concludes.
- Audio recorded sessions will be transcribed by SameDay Transcription, a HIPAA compliant company. Information disclosed outside the School of Nursing will be assigned a unique code number. Study investigators will ensure that the key to the code is kept in a locked file and destroyed at the end of the research study.
- Your authorization for use of your personal health information for this specific study does not expire.

Why is my information being used?
Your information is used by the research team to contact you during the study. And we will use your personal information to access your medical record. Your history and responses will be used to do the research.

Who may use and share information about me?
The following individuals may use or share your information for this study:

- The investigator for the study and the study team including research staff
- Other authorized personnel such as the Office of Human Research Protections at the University of Pennsylvania
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Once your personal health information is disclosed to others outside the School of Nursing, it may no longer be covered by federal privacy protection regulations.

Future Use of Data
Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected in this study.

Recordings of your coaching sessions will be stored for future research purposes. It is possible that a future researcher could identify you from your voice. This future research can be done without seeking your consent again in the future, as permitted by law. The future use of your information only applies to the information collected for this study.

None of your identifiers will linked to the voice recordings. Your information may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done. Possible future research may include analyses of the techniques used by the health coaches and the changes you experienced in response. We will not follow up with you to tell you about the specific research that will be done. We will give you any results from these studies, if you wish. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage by keeping the recordings in a security location that is monitored by the University of Pennsylvania. We will also be very careful in our review of any person wishing to use these data, with strict oversight of future studies. You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of how health coaching helps caregivers.

If you have questions about the storage of your information for future use or have changed your mind, you can contact Dr. Riegel at 215-898-9927. If you change your mind, we will remove your data from the set of data we use in future studies.

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. If you no longer wish to be in the research study, please leave a message with Dr. Riegel's Research Team at 215-898-5089 and she will remove you from the study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

You will receive a copy of this consent form and this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document, you are permitting the investigators to use and disclose personal health information collected about you for research purposes as described above.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date