SERENE

Supporting Evidence-based Responses to Emotional Needs in Emphysema

Combined Consent and HIPAA Authorization Forms

Principal Investigator	*Joanna Hart, MD, MSHP*
Study Sponsor	*National Institute of Nursing Research (NINR)*
Study Name	*Supporting Evidence-based Responses to Emotional Needs in Emphysema (SERENE)*
Version Number	2
Date	8/15/2024

Palliative & Advanced Illness Research (PAIR) Center
University of Pennsylvania

UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM

SERENE

Protocol Title:	Supporting Evidence-based Responses to Emotional Needs in Emphysema (SERENE)
Principal Investigator (PI):	Joanna Hart, M.D., M.S.H.P. 305 Blockley Hall 423 Guardian Drive Philadelphia, PA 19104-6021
Emergency Contact:	Joanna Hart, M.D., M.S.H.P. 267-271-0665

Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

Please be aware that there is a possibility that you may not be able to take part in this study. You will only be eligible if you have a loved one, friend, or support person who wants to join the study with you.

The purpose of the study is to learn which of two programs can best help people cope with lung disease. Coping Skills Training (CST) and COPD Education are approaches to help people with lung disease and their support person better manage COPD. Whether or not you are eligible will be decided by answering questions about your mood on a survey.

IRB Approved on: 8/15/2024

If you and your support person join the study, you will be randomized to join one of two programs (interventions) that will involve 12 weekly phone or videoconferencing sessions using Webex, Microsoft Teams, or Zoom. Randomization means that you are put into a group by chance. Two in three patients and their support people will be assigned to the CST group, while one in three will be assigned to the COPD Education group. There is no way to predict which group you will be assigned to. You will have a chance of being placed in either group.

You will complete surveys about your experiences and wellbeing before, during, and after the program. You can complete these surveys by phone, email, or in-person with a member of the study team. You will be compensated up to $100 for completing all surveys.

This study may or may not directly benefit you and/or your support person. Participating may help you better manage your stress and COPD symptoms. Additionally, your participation could help us understand how to better meet the emotional needs of patients with emphysema and/or COPD.

The most common risks of participation are the very low possibility that other people may find out private information that you tell the study team. Also, there is a chance that some of the study sessions and surveys can bring about uncomfortable emotions. Our study team takes specific measures to make sure the study has the most benefits and the least risk possible.

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time.

Why am I being asked to volunteer?

You are being asked to take part in a research study because you have COPD and/or emphysema and have identified an adult who can participate with you. You must also have the ability to access a telephone or videoconferencing call on Webex, Microsoft Teams, or Zoom once weekly (for approximately 30 minutes) for 12 weeks. You will need access to a device (e.g., cell phone, computer, or tablet) with a video and/or audio connection and internet or cellular data connection to participate. If you only have a phone (cell phone or landline) you can still participate.

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 other than you will not be able to participate in the programs the study offers. 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 you decide to participate. You do not have to make a decision now; you can take the consent document home and share it with friends 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 anything in this form. If you decide to participate, you will be asked to sign this form, and a copy of the form will be given to you so that you can find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to learn which of two different programs can best help people cope with lung disease. The study will also learn how these programs can be made to work best for people participating in them.

How long will I be in the study?

The study will last for 26 weeks, or about 6 months. First, you will have a screening session. After that, you will join a 12-week program (intervention) with one session per week. After you finish the 12 sessions, you will do four surveys over the next 14 weeks. You might also be asked to do an optional interview after the screening, during the program, or after it ends. You can schedule the interview when it works best for you.

What am I being asked to do?

If you are interested in joining the study, you must join with another adult. This adult can be a family member or close friend who spends time with you (in person or by phone), lives with you, participates in household duties with you, learns about your health with you, helps you schedule or get to your appointments, knows about your medications, and/or assists you with day-to-day activities.

The study consists of a 12-week program led by a trained member of the study team. Both programs are designed to help you to manage with the symptoms of COPD and/or emphysema. Regardless of which program you are in, you will have weekly meetings. In the CST group, you will participate in structured sessions that focus on building coping skills. In the COPD Education group, you will receive structured sessions that focus on learning about COPD. The length of the sessions will vary depending on the group you are in. Sessions for the CST group will last for 30 minutes, while sessions for the COPD Education group will last about 10 minutes.

As part of either program, you will receive additional materials in the mail. You will receive reminders about the sessions through phone calls, emails, text messages, and/or myPennMedicine.

To ensure the weekly sessions are delivered consistently across participants, some sessions will be audio and/or video recorded. Audio and/or video recordings will be identified and stored using study IDs only on secure servers used for storing protected health information. The session recordings will only be used to make sure that the study

team member is leading the program according to the plan. A member of the study team will ask for your permission before ever recording a session. If you do not provide permission for the recording to take place, you will be asked if you wish to opt out of subsequent recordings.

You will fill out surveys before the first session of the program, at about week 5 and 7 during the program, at the end of the last session, and 2, 12, and 14 weeks after the last session. Depending on the group you are assigned to, you may be asked to respond to brief questions about individual sessions. You may complete these surveys online using a link sent by text message, myPennMedicine or email to you, over the phone with a study team member, or in-person with a study team member. Surveys are hosted on a secure platform designed to collect data called REDCap. Text messages are sent using a platform called Mosio.

For both patients and the people who support them, there is an option to participate in a phone interview to talk about your experiences with the program. This interview will take place by phone or video conference on Webex, Microsoft Teams, or Zoom and will be audio recorded. We will conduct these interviews after the program has finished. This interview will take about 30-40 minutes. The study team will select people who complete the surveys to take part in an interview. We will contact you if you are selected to schedule the interview session. Anyone who chooses not to take part in the study will also have the opportunity to participate in an interview to talk about why they made that decision.

What are the possible risks or discomforts?

There are no known medical risks for this study.

The primary risk from this study comes from a potential breach of confidentiality. This means people outside the study learning about your private information. To reduce the risk of this, all of the information you provide will be stored on secure computers or, in the case of written or recorded material, in a physically locked cabinet within a locked office. Only people helping to run the study will have permission and access to your information and only the information they need to do their jobs.

A second possible risk to you is emotional distress caused by reading and responding to potentially upsetting questions either during the surveys or participating in the program. If you become emotionally upset, you may stop your participation at any time. The research staff can provide you with information about resources for counseling. At times, if we notice you are upset, we may pause the program and get more information on how to support you.

If you are experiencing distress and would like the research team to provide these resources or support for you, please notify any member of the research team.

What are the possible benefits of the study?

This study may or may not directly benefit you and/or your support person. Participating may help you better manage your stress and COPD symptoms. Also, your participation could help us understand how to better meet the emotional needs of patients with COPD, which can benefit you indirectly. Participating in either group may help you better manage your stress and COPD symptoms.

What other choices do I have if I do not participate?

Your alternative to being in the study is to not be in the study. This will in no way impact or alter the care that you receive, except that you will not be able to participate in the offered programs. 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 outside the study or would come to you in the future. Your doctor, nurse, or therapist will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

Will I be paid for being in this study?

You may be paid up to $100 for completion of all study surveys. Payment will be divided up and given to you according to the following schedule:

- $10 for completion of the survey before the first session of the program
- $10 for completion of the survey at 5 weeks into the program
- $10 for completion of the survey at 7 weeks into the program
- $15 for completion of the survey at the end of the last session of the program
- $15 for completion of the survey 2 weeks after the last session of the program
- $15 for completion of the survey 12 weeks after the last session of the program
- $25 for completion of the survey 14 weeks after the last session of the program

If you participate in an interview, you will receive $25 for completing it.

You will be paid for each survey you complete. Payments can be made through the Greenphire Visa ClinCard, a secure and rapid payment method. The ClinCard is a reloadable debit card that can be used at any merchant that accepts Visa, as well as at ATMs or banks to withdraw cash.

Will I have to pay for anything?

There are no costs to you associated with participating in this study. However, you must have access to a phone, tablet, or computer in order to complete the sessions and surveys. If you only have a phone or access to a phone, you may participate. Your phone company may charge for receiving text messages or using data or internet service – this depends on your plan. You can opt out of text messaging. All study activities can be completed by phone. You will be able to choose your preferred method of communication for participating.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health. You will be informed of the reasons why.
- You have not followed the study instructions. The study team will make up to five contact attempts through phone calls, emails, text messages, and/or myPennMedicine to assist you with the study tasks.
- The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania decides to stop the study.

You also have the right to drop out of the research study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so, other than the remaining participation payments and the remaining parts of the study program. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Dr. Joanna Hart (Principal Investigator) at 267-271-0665 or Joanna.Hart@pennmedicine.upenn.edu. There will be no consequences for withdrawing from the study other than that you will no longer receive money from the study and will not be able to participate in the program offered to you. If you withdraw from the study, your data will be destroyed only if you request this. You may do this by contacting the Principal Investigator.

How will my personal information be protected during the study?

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. Your personal information may be given out if required by law. Some examples are laws that require reporting of child or elder abuse and threats to harm yourself or others. If information from this study is published or presented at scientific meetings,

your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The Principal Investigator and staff involved with the study will keep your personal and medical information collected for the study strictly confidential. It will be kept in a secured file.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

Your responses, as well as the responses from other participants in this study, will be used to learn about how two programs can better support the mental and emotional needs of patients with COPD.

For this study, we will collect the following information:

- Name.
- Personal characteristics such as date of birth, address, phone number, email address, gender identity, race, and level of education.
- Medical record number.
- Medical history, including behavioral health treatments.

Study information about you will not be given to you or others (unless it is required by a government agency or other legal authority). This means that no one (not you, the support person who joins the study with you, your family, your doctor, your insurance company, or your employer) will have access to this information during the study.

Once your personal or medical information is shared with someone who is not a health care provider, it is not protected by the US federal privacy rules (called HIPAA). When you sign this consent form, you agree to have your personal and medical information used as described here.

An exception to this is that we may tell your pulmonary or primary care teams limited information if your pulmonary symptoms seem severe or worse. We would tell them only so that they can help care for you. If a trained member of the study team notices that you have worsening of your pulmonary symptoms, like significant shortness of breath or coughing, we will tell your clinical team so they can support you.

If you allow us to record the audio or video of a session, this information will only be shared within the study team, including a member of the study team at Thomas Jefferson University, to ensure the program is delivered according to the plan. Once this check is complete, the recordings will be deleted.

If you allow us to record an interview, we will send the audio recording to a company that specializes in transcribing audio into written documents. This company follows strict rules to protect your personal information. After the audio is turned into a written document, any information that could be used to identify you, like your name or home address, will be taken out. Once the written document is ready, we will check it for accuracy and then delete the original audio recording. This written document will only be used to ensure the study team member is leading the program consistently for all participants.

Future Use of Data

Your information will be de-identified. De-identified means that all identifiers (such as name, date of birth, medical record number, date of hospitalization, address, etc.) 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 on this study. If you change your mind, we will not be able to destroy or withdraw your information that was shared because all identifiers would have already been removed.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research.
- Oversee the research.
- See if the research was done right.
- Evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical research management system (PennCRMS). This system is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other

activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team.
- The independent safety monitor (a University of Pennsylvania faculty member who ensures the study is safe for participants).
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

All people who have access to your information have undergone formal training in research standards prior to their work on this study.

Who, outside of Penn Medicine, might receive my information?

- Those working under the direction of the investigator for the study (e.g., under subcontracts).
- All research centers participating in the study, even if they are not part of Penn Medicine. This also includes a study investigator at Thomas Jefferson University who will review some session recordings to ensure they are being delivered as they were designed and for training purposes.
- The funding Sponsor (National Institute of Nursing Research) and organizations supporting the sponsor.

Oversight organizations

- The U.S. Office of Human Research Protections (OHRP).
- The study's independent safety monitor.

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization.
- The University of Pennsylvania's Institutional Review Board grants permission.
- As permitted by law.

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. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this 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 research study.

You will be given a copy of this research participant informed consent form and HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

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

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 participant, 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 IRB at the number on page one of this form.

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 protected health information collected about you for research purposes within our institution.

You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date

Communication and recording permissions

Can we send you text messages with reminders and survey links?

Text messaging is not completely secure and may cost money based on your phone plan. We suggest deleting text messages after you read them to protect your privacy. You can say no now or opt out later if you change your mind.

- ☐ Yes, I give permission to receive text messages.
- ☐ No, I don't give permission to receive text messages.

Can we record audio and/or video of some sessions to see how well the program is being delivered to you?

These recordings will only be used to make sure the session is being delivered according to the program plan and will be deleted after they are reviewed by the study team.

- ☐ Yes, I give permission to record AUDIO AND/OR VIDEO of some sessions.
- ☐ Yes, I give permission to record ONLY AUDIO of some sessions.
- ☐ No, I don't give permission to record audio or video of some sessions.

UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM

SERENE

Protocol Title:	Supporting Evidence-based Responses to Emotional Needs in Emphysema (SERENE)
Principal Investigator:	Joanna Hart, M.D., M.S.H.P. 305 Blockley Hall 423 Guardian Drive Philadelphia, PA 19104-6021
Emergency Contact:	Joanna Hart, M.D., M.S.H.P. 267-271-0665

Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

Please be aware that there is a possibility that you may not be able to take part in this study. You can join the study only if you sign up with someone who has a lung disease and you help them.

The purpose of the study is to learn which of two programs can best help people cope with lung disease. These programs are delivered by research staff who are not clinicians. Coping Skills Training (CST) and COPD Education are approaches to will help people with lung disease and their support person better manage COPD.

If you are eligible, you and the person you support will be randomized to join one of two programs (interventions) that will involve 12 weekly phone or videoconferencing sessions using Webex, Microsoft Teams, or Zoom. Randomization means that you are put into a group by chance. Two in three patients and their support people will be assigned to the CST group, while one in three will be assigned to the COPD Education group. There is no way to predict which group you will be assigned to. You will have a chance of being placed in either group.

You will complete surveys about your experiences and well-being before, during, and after the program. You can complete these surveys by phone, email, or in-person with a member of the study team. You will be compensated up to $100 for completing all surveys.

This study may or not directly benefit you and/or the person you support. Participating may help you and the person you support to better manage stress and their COPD symptoms. Additionally, your participation could help us understand how to better meet the emotional needs of patients with emphysema and/or COPD.

The most common risks of participation are the very low possibility that other people may find out private information that you tell the study team. Also, there is a chance that some of the study sessions and surveys can bring about uncomfortable emotions. Our study team takes specific measures to make sure the study has the most benefits and the least risk possible.

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time.

Why am I being asked to volunteer?

You are being asked to take part in a research study because you support a person with COPD and/or emphysema. You must also have the ability to access a telephone or videoconferencing call on Webex, Microsoft Teams, or Zoom once weekly (for approximately 30 minutes) for 12 weeks. You will need access to a device (e.g., cell phone, computer, or tablet) with a video and/or audio connection and internet or cellular data connection to participate. If you only have a phone (cell phone or landline) you can still participate.

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 or the person you support are otherwise entitled other than you will not be able to participate in the programs the study offers. 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 you decide to participate. You do

not have to make a decision now; you can take the consent document home and share it with friends 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 anything in this form. If you decide to participate, you will be asked to sign this form, and a copy of the form will be given to you so that you can find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to learn which of two different programs can best help people cope with lung disease. They study will also learn how these programs can be made to work best for people participating in them.

How long will I be in the study?

The study will last for 26 weeks, or about 6 months. This means that after this initial screening session, you will participate in a 12-week program (intervention). After you finish the 12 sessions, you will do four surveys over the next 14 weeks. You might also be asked to do an optional interview after the screening, during the program, or after it ends. You can schedule the interview when it works best for you.

What am I being asked to do?

To enroll in the study, you must join with a person who has COPD and/or emphysema. You must provide some unpaid or paid support. You could be their family member or close friend who spends time with the person (in person or by phone), lives with them, participates in household duties with them, learns about their health with them, helps them schedule or get to their appointments, knows about their medications, and/or assists them with day-to-day activities.

The study consists of a 12-week program led by a trained member of the study team. Both programs are designed to help you and the individual with COPD and/or emphysema to manage the symptoms of these conditions. Regardless of which program you are in, you will have weekly meetings. In the CST group, you will participate in structured sessions that focus on building coping skills. In the COPD Education group, you will receive structured sessions that focus on learning about COPD. The length of the sessions will vary depending on the group you are in. Sessions for the CST group will last for 30 minutes, while sessions for the COPD Education support group will last about 10 minutes.

As part of either program, you will receive additional materials in the mail. You will receive reminders about the sessions through phone calls, emails, text messages, and/or myPennMedicine.

To ensure the weekly sessions are delivered consistently across participants, some sessions will be audio and/or video recorded. Audio and/or video recordings will be identified and stored using study IDs only on secure servers used for storing protected health information. The session recordings will only be used to make sure that the study team member is leading the program according to the plan. A member of the study team will ask for your permission before ever recording a session. If you do not provide permission for the recording to take place, you will be asked if you wish to opt out of subsequent recordings.

You will fill out surveys before the first session of the program, at about week 5 and 7 during the program, at the end of the last session, and 2, 12, and 14 weeks after the last session. Depending on the group you are assigned to, you may be asked to respond to brief questions about individual sessions. You may complete these surveys online using a link sent by text message, myPennMedicine or email to you, over the phone with a study team member, or in-person with a study team member. Surveys are hosted on a secure platform designed to collect data called REDCap. Text messages are sent using a platform called Mosio.

For both patients and the people who support them, there is an option to participate in a phone interview to talk about your experiences with the program. This interview will take place by phone or video conference on Webex, Microsoft Teams, or Zoom and will be audio recorded. We will conduct these interviews after the program has finished. This interview will take about 30-40 minutes. The study team will select people who complete the surveys to take part in an interview. We will contact you if you are selected to schedule the interview session. Anyone who chooses not to take part in the study will also have the opportunity to participate in an interview to talk about why they made that decision.

What are the possible risks or discomforts?

There are no known medical risks for this study.

The primary risk from this study comes from a potential breach of confidentiality. This means people outside the study learning about your private information. To reduce the risk of this, all of the information you provide will be stored on secure computers or, in the case of written or recorded material, in a physically locked cabinet within a locked office. Only people helping to run the study will have permission and access to your information and only the information they need to do their jobs.

A second possible risk to you is emotional distress caused by reading and responding to potentially upsetting questions either during the surveys or participating in the program. If you become emotionally upset, you may stop your participation at any time. The research staff can provide you with information about resources for counseling. At times, if we notice you are upset, we may pause the program and get more information on how to support you.

If you are experiencing distress and would like the research team to provide these resources or support for you, please notify any member of the research team.

What are the possible benefits of the study?

This study may or may not directly benefit you and/or the person you support. However, your participation could help us understand how to better meet the emotional needs of patients with COPD, which can benefit you and the person you support indirectly. Participating in either group may help the person with COPD to better manage their stress and COPD symptoms.

What other choices do I have if I do not participate?

Your alternative to being in the study is to not be in the study. This will in no way impact or alter the care that the person with COPD will receive, except that you will not be able to participate in the offered programs. 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 and the person you support will lose no benefits or advantages that are now coming to you, or would come to you in the future. The doctor, nurse, or therapist will not be upset with your decision.

If the person you support is currently receiving services and you choose not to volunteer in the research study, their services will continue.

Will I be paid for being in this study?

You may be paid up to $100 for completion of all study procedures. Payment will be divided up and given to you according to the following schedule:

- $10 for completion of the survey before the first session of the program
- $10 for completion of the survey at 5 weeks into the program
- $10 for completion of the survey at 7 weeks into the program
- $15 for completion of the survey at the end of the last session of the program
- $15 for completion of the survey 2 weeks after the last session of the program

- $15 for completion of the survey 12 weeks after the last session of the program
- $25 for completion of the survey 14 weeks after the last session of the program

If you participate in an interview, you will receive $25 for completing it.

You will be paid for each survey you complete. Payments can be made through the Greenphire Visa ClinCard, a secure and rapid payment method. The ClinCard is a reloadable debit card that can be used at any merchant that accepts Visa, as well as at ATMs or banks to withdraw cash.

Will I have to pay for anything?

There are no costs to you associated with participating in this study. However, you must have access to a phone, tablet, or computer in order to complete the sessions and surveys. If you only have a phone or access to a phone, you may participate. Your phone company may charge for receiving text messages or using data or internet service – this depends on your plan. You can opt out of text messaging. All study activities can be completed by phone. You will be able to choose your preferred method of communication for participating.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health. You will be informed of the reasons why.
- You have not followed the study instructions. The study team will make up to five contact attempts through phone calls, emails, text messages, and/or myPennMedicine to assist you with the study tasks.
- The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania decides to stop the study.

You also have the right to drop out of the research study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so, other than the remaining participation payments and the remaining parts of the study program. Withdrawal will not interfere with your future care or that of the person you support.

If you no longer wish to be in the research study, please contact Dr. Joanna Hart (Principal Investigatory) at 267-271-0665 or Joanna.Hart@pennmedicine.upenn.edu. There will be no consequences for withdrawing from the study other than that you will no longer receive money from the study and will not be able to participate in the

program offered to you. If you withdraw from the study, your data will be destroyed only if you request this. You may do this by contacting the Principal Investigator.

How will my personal information be protected during the study?

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. Your personal information may be given out if required by law. Some examples are laws that require reporting of child or elder abuse and threats to harm yourself or others. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The Principal Investigator and staff involved with the study will keep your personal and medical information collected for the study strictly confidential. It will be kept in a secured file.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

Your responses, as well as the responses from other participants in this study, will be used to learn about how two programs can better support the mental and emotional needs of patients with COPD.

For this study, we will collect the following information:

- Name.
- Personal characteristics such as date of birth, address, phone number, email address, gender identity, race, and level of education.

Study information about you will not be given to you or others (unless it is required by a government agency or other legal authority). This means that no one (not you, the person with COPD, your family, your doctor, your insurance company, or your employer) will have access to this information during the study.

Once your personal or medical information is shared with someone who is not a health care provider, it is not protected by the US federal privacy rules (called HIPAA). When you sign this consent form, you agree to have your personal and medical information used as described here.

If you allow us to record the audio and/or video during any of the program sessions, we will send the audio recording to a company that specializes in transcribing audio into written documents. This company follows strict rules to protect your personal information. After the audio is turned into a written document, any information that could be used to identify you, like your name or home address, will be taken out. Once the written document is ready, we will check it for accuracy and then delete the original audio recording. This written document will only be used to ensure the study team member is leading the program consistently for all participants.

Future Use of Data

Your information will be de-identified. De-identified means that all identifiers (such as name, date of birth, address, etc.) 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 on this study. If you change your mind, we will not be able to destroy or withdraw your information that was shared because all identifiers would have already been removed.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research.
- Oversee the research.
- See if the research was done right.
- Evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical research management system (PennCRMS). This system is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team.
- The independent safety monitor (a University of Pennsylvania faculty member who ensures the study is safe for participants)
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

All people who have access to your information have undergone formal training in research standards prior to their work on this study.

Who, outside of Penn Medicine, might receive my information?

- Those working under the direction of the investigator for the study (e.g., under subcontracts).
- All research centers participating in the study, even if they are not part of Penn Medicine. This also includes a study investigator at Thomas Jefferson University who will review some session recordings to ensure they are being delivered as they were designed and for training purposes.
- The funding Sponsor (National Institute of Nursing Research) and organizations supporting the sponsor.

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- The study's independent safety monitor.

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization.
- The University of Pennsylvania's Institutional Review Board grants permission.
- As permitted by law.

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. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this 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 research study.

You will be given a copy of this research participant informed consent form and HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

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

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 participant, 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 IRB at the number on page one of this form.

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 protected health information collected about you for research purposes within our institution.

You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date

Communication and recording permissions

Can we send you text messages with reminders and survey links?

Please note that text messaging is not completely secure and may cost money based on your phone plan. We suggest deleting text messages after you read them to protect your privacy. You can say no now or opt out later if you change your mind.

- ☐ Yes, I give permission to receive text messages.
- ☐ No, I don't give permission to receive text messages.

Can we record audio and/or video of some sessions to see how well the program is being delivered to you?

These recordings will only be used to make sure the session is being delivered according to the program plan and will be deleted after they are reviewed by the study team.

- ☐ Yes, I give permission to record AUDIO AND/OR VIDEO of some sessions.
- ☐ Yes, I give permission to record ONLY AUDIO of some sessions.
- ☐ No, I don't give permission to record audio or video of some sessions.