Institutional Review Board
Informed Consent Document for Research
MASTER INFORMATION SHEET

Study Title: RESOLVE
Version Date: 12/28/2022

Part 1 of 2: MASTER INFORMATION SHEET

You are being invited to take part in a research study. This study will take place at several different locations. Therefore, this information sheet includes two parts. Part 1 is the Master Information Sheet and includes information that applies to all study sites. Part 2 is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are part of the informed consent process and must be provided to you. You can complete the informed consent process online or over the phone with a study team member. You will have the opportunity to ask questions on the phone. If you are completing the informed consent process online, you can call the study to ask questions. You will be asked to give your consent after you have had the opportunity to ask questions.

Researchers
This study is led by Lynn DeBar, PhD, Kaiser Permanente Northwest

Funder
The RESOLVE study is funded by the National Institute on Aging.

Key information about this study:

RESOLVE is a research study that will compare three different services to help patients learn skills to manage pain. These services include a printed resource guide, access to an online training program, or access to a training program with a live coach who would meet with you by phone or video. The skills taught in the online and telephone programs are based on Cognitive Behavioral Therapy, or "CBT," a type of therapy that helps people think about and respond to challenging situations, like having chronic pain. If you join the RESOLVE study, you will be assigned randomly to get one of these three services. There will be no cost to you to receive the services. We will collect some information from your medical record about care provided to you. We will also ask you to complete five surveys and up to two interviews over the next year. You will be in the study for 12 months. While you are in the study, you can use any treatments or services recommended by your doctor. About 2,400 people will take part in this research study.

Study Title: RESOLVE
Version Date: 12/28/2022

Being in this study is up to you. If you decide not to be in this research study, or drop out later, it won't affect the health care you receive or benefits you are entitled to. If you join, you can stop being in this study at any time.

Risks that you can expect if you take part in this study:

You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.

You might feel uncomfortable practicing new pain management skills. For example, it might be challenging to change your thoughts or behaviors related to your pain; or, it might be hard to change physical activity patterns.

It is possible that someone other than the researchers could find out you were in the study or see your private study information. The steps we take to keep this from happening are described in Part 2 of this information sheet.

Positive effects that might result from this study:

We cannot promise any direct benefits to you or others by taking part in this research. However, some people who received the pain management tools used in this study experienced improvements in their pain.

Procedures to be followed:

If you are interested in being in this study, we will ask you to answer a few questions over the phone or online to find out if you are eligible. Some of the questions are on sensitive topics such as substance use. You don't have to answer any questions you don't want to. However, without your answers we won't know if you are eligible to join the study.

If you join the study, we will ask you to:

- **Complete a baseline survey** that will last about 30-45 minutes (survey #1). You will do the survey as soon as you join the study. You can choose to complete it over the phone or online. The survey will ask questions about your pain and how it affects your life. Some of the questions are on sensitive topics such as mental health and substance use. You can skip any question you do not want to answer.

Be randomly assigned to get 1 type of service over the course of 8-12 weeks. After you complete the baseline survey, a computer will randomly assign you to 1 of 3 study "groups" – like a coin toss or like drawing straws. Each group gets only 1 of the 3 services for pain management offered in the study. You have an equal chance of being placed in any 1 of these 3 groups. You cannot choose which group you will be in. We will mail you a packet about a week after the baseline survey to tell you which group you are in. You also cannot change the group after you've been assigned.

- **Group 1** will be mailed a printed resource guide on managing chronic pain. If you are assigned to this group, you would read and use the guide on your own.

- **Group 2** will receive access to an online training program. The skills taught in the web-based program are based on Cognitive Behavioral Therapy, or "CBT," a type of therapy that helps people think about and respond to challenging situations, like chronic pain. There are 8 sessions in the online program and each session takes about 45-60 minutes. If you are assigned to this group, you would complete one session each week and have 12 weeks to complete all 8 sessions.
    - In addition, you would need to register on the program website with an email address and accept the Terms and Conditions and Privacy Policy. The website will track your online activity and record when you log in. If your internet or mobile phone service requires you to pay for the data you use, using the online program may result in data usage fees from your service provider. The program uses a minimal amount of data.

- **Group 3** will receive access to a telephone training program with a live coach who teaches CBT skills. There are 8 sessions in this training program and each session would take about 60 minutes. If you are assigned to this group, you would complete on session each week and have 12 weeks to complete all 8 sessions. You can choose to use video with the telephone calls or use only voice with the telephone calls.
    - In addition, we will ask for your permission to audio record the telephone-only sessions or video record the video sessions. The recordings will be used for quality and training purposes. You can still participate in the sessions even if you do not agree to have the

conversation recorded. If your internet or mobile phone service requires you to pay for the data you use, joining the video calls may result in data usage fees from your service provider.

- **Complete a brief paper survey** that will take about 5 minutes (survey #2). It will come with the mailed packet you get telling you which group you are in. This survey should be completed right away and mailed back in the pre-paid envelope provided.

- **Complete 3 follow-up surveys** about 3 months, 6 months, and 12 months after you join the study that will take about 30 minutes each (surveys #3, 4 and 5). You can choose to do the surveys over the phone, on paper, or online. The surveys will ask questions about your pain and how it affects your life. Some of the questions are on sensitive topics such as mental health and substance use. You can skip any question you do not want to answer.

- **Let us collect some information from your medical record about health care provided to you for the past year and for the 12 months that you are in the study.** This will help us better understand how well the program works and the costs of health care services you use. We won't look at the notes your doctor writes or any bills sent to you or payments you've made. Instead, we will use a computer to collect information on the health services you use and calculate the typical costs of those services. We will collect information about all doctor visits, trips to the hospital, medications (including opioid and other pain medications) and diagnoses (including behavioral health diagnoses.) We will also collect information about you, including your age and ethnic background. Your medical record information will be linked with your survey answers.

- About 120 of the 2,400 people who participate in the study will be selected to complete up to two, optional, **hour-long telephone interviews** about their experiences with pain management and being in the study. You may not be selected, and if you are, you don't have to be interviewed.

You will receive Amazon gift cards to thank you for the surveys and interviews you do. These are the amounts you can receive.

- **Baseline survey:** $25
- **3-month survey**: $30 if done by phone or paper; $35 if done online

- **6-month survey**: $35 if done by phone or paper; $40 if done online
- **12-month survey:** $40 if done by phone or paper; $45 if done online
- **Interviews**: $30 per interview (up to two interviews)

Clinical Trials Registry

A description of this clinical trial is 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. [ClinicalTrials.gov Identifier: NCT04523714]

Institutional Review Board
Informed Consent Document for Research
STUDY SITE INFORMATION

Study Title: RESOLVE
Version Date: 03/14/22

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Kaiser Permanente Georgia
Site Principal Investigator:	Courtney McCracken, PhD.
Site Principal Investigator Contact:	404364-3834
Site Study Coordinator	Musu Sesay
Site Study Coordinator Contact	404-364-7190

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you.

Who to call for any questions:

Please call the Site Study Coordinator, Musu Sesay, at 404-364-7190.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Protecting your confidentiality

This study is led by researchers at Kaiser Permanente (KP) Washington, KP Northwest, KP Georgia, and Essentia Health. They are listed on Part 1 of this information sheet. This study also includes researchers at Northwestern University who manage the online coaching program and researchers at the University of Utah who manage the study database. These researchers each signed a pledge at their institution that requires them to keep your information private. The researchers and their staff will use your study information for research only.

The researchers are involved in different parts of the study. So, your study information will be stored in different places.

- Research staff at KP Washington, KP Northwest, and University of Utah will have **your contact information**. They will communicate with you if you are placed in the online coaching group or the telephone coaching group. They will also communicate with you to complete surveys and interviews.
- **Your survey answers** will be entered into a secure website and stored on secure servers at KP Northwest and the University of Utah.
- **Your medical record information** will be linked with your survey answers and stored on secure servers at KP Northwest and the University of Utah.
- **Audio- and video recordings** will be stored on secure servers at KP Northwest and KP Washington.
- **Interview transcripts** will be stored on secure servers at KP Northwest.
- If you are placed in the online coaching group, information about **your activity on the website** will be stored on secure servers at Northwestern University and KP Northwest.

We won't use your name in study reports or write it on your survey answers or audio- and video recordings. Instead, we will label everything with a code number only. Your information will be stored in locked offices and secure computer servers.

We plan to keep your study information as described in this form until August 31, 2027. At that time, we will destroy any study records that could identify you.

Future use

At the end of the study, the data will be stored indefinitely by the NIH or a data center selected by the NIH to enable future research use. Your name and other personally-identifying information will not be kept with the final research data.

This study is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and analyze them in different ways. Therefore, your data will be used for this and other NIH HEAL Initiative

studies. Your stored data will also be made widely available to other researchers. The shared data may be used indefinitely for research not related to this study or the HEAL Initiative, without asking you for additional consent.

If you withdraw from this research study before it is done, we will keep and continue to use data that have already been collected.

Certificate of Confidentiality

We have a Certificate of Confidentiality from the National Institute on Aging. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you, even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

In certain situations, we would not be able to keep your information confidential. The law requires us to report in cases of a medical emergency or serious threats of harm to you or others.

Using email

We will ask you for your email address. You do not have to give us your email address. However, if you are placed in the online coaching group, you will need to use your email address to register for the website. Information shared by email is not considered secure. We cannot guarantee the privacy of email, and we will be careful to limit the amount of personal information included in messages we send you. These are the kinds of information we will send you by email:

- Schedule study appointments
- Send reminders for study appointments and surveys
- Send electronic gift cards for completing surveys and interviews

- If you are placed in the online coaching group, links to the website
- If you are placed in the telephone coaching group and want to do a video call, links to video calls

Texting

If you are placed in the telephone coaching group, research staff may use a study cell phone to text you if they have not been able to reach you using other methods (phone call, email or letter).

How HIPAA applies to this study

Your health information is protected by a federal privacy law called HIPAA. KP Georgia must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By agreeing to participate in this study, you are giving KP Georgia permission to allow the researchers to collect, use, and share the following information about you with our research collaborators:

1. Your survey and interview answers
2. Your medical record information as described in Part 1 of this information sheet
3. If you are placed in the online coaching group, your activity on the website

It is possible that staff from KP Georgia, our research collaborators, and other organizations may look at our study records to make sure the study is being conducted according to regulations. The other organizations are:

- The Vanderbilt University Institutional Review Board (a committee of scientific, non-scientific, and community members who review research to protect the rights and welfare of participants)
- A Data Safety Monitoring Board
- The National Institute on Aging, which is the funding agency for the RESOLVE study

We will not share the information we collect for this study with anyone else except as allowed by law.

The HIPAA privacy law does not always apply to those who are given protected health information. If your health information is given to an organization not covered by laws protecting health information, it can be further disclosed.

However, all of the research centers involved in this study have made agreements to protect your health information.

In order to be in the study, you must agree to this use of your health information. This permission for the researchers to obtain your health information for this study ends on August 31, 2027, when we will destroy any records that include your name or other identifying information.

If you change your mind

You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:

Courtney McCracken, PhD.
Kaiser Permanente Georgia
Center for Research and Evaluation
1375 Peachtree Road, N.E., Suite 380
Atlanta, GA 30309

If you take back your consent, it will not affect your health care or benefits at KP Georgia. We may still use the study information we collected before we received the letter taking back your consent. But we will destroy any record of your name or other information that could identify you.