The Development of an Integrated Physical Activity and Mental Health Intervention for Veterans with COPD, Emotion Distress, and Low Physical Activity

ClinicalTrials.gov ID NCT04953806

Informed Consent Form (Effective Version Date: 12/08/2025)

Participant Name: _____ Date: _____

Title of Study: **The Development of an Integrated Physical Activity and Mental Health Intervention for Veterans with Chronic Obstructive Pulmonary Disease (COPD), Emotion Distress, and Low Physical Activity: Feasibility of Step-CBT in Veterans with COPD and Emotional Distress (Study 3)**

Principal Investigator: **Patricia M. Bamonti, PhD** VA Facility: **VA Boston Healthcare System**

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veteran Affairs, Rehabilitation Research and Development Service Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about ways of promoting physical activity and improving depression (e.g., low mood) and/or anxiety symptoms (e.g., worry). Your participation in this research will last about 11 weeks or about 3 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no known direct benefits to you for being in this study. Your participation will help us better understand the relationship between Chronic Obstructive Pulmonary Disease (COPD) and mental health. *For a complete description of benefits, refer to the Detailed Information section of this form.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You will participate virtually for all parts of the research study. Virtual video conferencing platforms, VA Video Connect (VVC) or Cisco Webex, will be used for the research study visits. If you choose to participate and use the virtual platforms, you agree to voluntarily provide an email address that you will use to receive VA emails and access the virtual video platform. Although Cisco Webex is secure and fully VA-authorized, it is not a VA site and is not controlled, monitored, or managed by the VA.

Participation in this study involves wearing two physical activity monitors. If you are uncomfortable wearing a device which measures your physical activity, you may not want to participate in this study.

You will be asked to answer questionnaires about yourself and your physical activity and you will complete a brief test of your thinking and memory. It is possible that some questions on the questionnaires may make you feel uncomfortable. You do not need to answer these questions. You can take breaks if you feel inconvenienced or fatigued.

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In addition, the Step-Cognitive Behavioral Therapy (Step-CBT) intervention includes wearing a device called a Fitbit pedometer that measures your daily step count (i.e., how much you walk), creating step count goals, and working with a psychologist on a weekly basis for a total of 8 sessions to target depression or anxiety symptoms.

This intervention presents minimal risk since you have been deemed medically stable by your usual healthcare provider. There are some potential risks related to walking and exercise. *For a complete description of risks, refer to the Detailed Information section of this form.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Patricia Bamonti, PhD, Principal Investigator (PI) at the VA Boston Healthcare System – Jamaica Plain. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted] (anytime) or [redacted] (Mon-Fri 8:00-4:30).

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Participant Name: _____ Date: _____

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Principal Investigator: **Patricia M. Bamonti, PhD** VA Facility: **VA Boston Healthcare System**

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

We are asking you to be in a research study that is being supported by the Department of Veteran Affairs (VA) Rehabilitation Research and Development Service. We are doing research to examine ways of promoting physical activity and improving depression (e.g., low mood) and/or anxiety symptoms (e.g., worry). We plan to enroll 50 Veterans.

HOW LONG WILL I BE IN THE STUDY?

If you agree to be in this study and are found eligible, you will be in the study for about 11 weeks or about 3 months if you decide to stay for the whole study. You will take part in two virtual study visits using VA Video Connect (VVC) or Cisco Webex, each lasting approximately two hours. You will be asked to participate in an 8-session virtual intervention using VA Video Connect (VVC) or Cisco Webex. You will also be asked to wear two devices that measure step count throughout your participation in the study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you participate in this study, you will continue to receive all of your medical care services. Taking part in this research is completely voluntary, and you may withdraw from the study at any time. If you decide to leave the study, your regular medical care and health benefits will not be affected.

You will be asked to give research staff permission to contact your usual healthcare provider. Research staff will contact your usual healthcare provider to confirm that it is medically safe for you to engage in an exercise intervention.

Using the US Postal Service (USPS), we will send you all the materials you will need throughout the duration of the study.

At the first study visit, you will be asked to complete additional screening:

- You will be asked to undergo an assessment of thinking and memory.
- You will be asked to perform a repeated chair stand test that involves standing from and sitting in a chair several times. You may get out of breath, but you will be able to slow

down or stop and rest as necessary. If you feel unsafe performing this test, you do not need to perform the test.

You will be eligible to participate based on your scores and performance on these screening measures.

If you are eligible to participate, you will be asked to complete the following:

- You will be asked to provide information about yourself, such as your age and race, and about your medical history, such as your medications, health conditions, and smoking history.
- You will voluntarily provide the telephone number and email at which we may contact you during the study.
- You will complete questionnaires that measure your mental health, physical health, pain, and quality of life.
- You will be provided a Fitbit pedometer and an ActiGraph to wear for 7 days while going about your usual activities to measure how much walking and activity you do normally. During this time, you will be asked not to check your step counts except to record your daily step count on a record log each night prior to bedtime. You will mail back the Actigraph in a pre-paid mailer.
- Once you start the intervention, you will be asked to wear the Fitbit during waking hours and you will continue to track your step counts on a record log given to you.
- At the end of the intervention, you will be asked to keep wearing the Fitbit and will be mailed back the Actigraph to wear for another 7 days. This will occur around week 9-10 of the study. You do not have to keep track of these dates, we will do that for you.
- The ActiGraph has no screen and you only need to record the times you take off the device and the reasons for non-wear (e.g., showering) using the log provided.
- You will be asked to download the Fitbit app on your personal smartphone or iPad or loaned study iPad.
- If you are provided with a loaned study iPad, we ask that you do not use it for any other purposes other than those related to this study (i.e., downloading Fitbit app, attending VVC/Cisco Webex study sessions). Please do not enter or store any personal information on this device.

- If you voluntarily choose to use the Fitbit app, then the company will have access to this information. If you choose to use the Fitbit and Fitbit app, we will create a study-specific account login and password on the publicly available, commercial app for Fitbit. This is not a VA app and is not controlled, monitored, or managed by the VA. We will show you the Fitbit app and encourage you to read their privacy policy.
- The Fitbit app is used only to sync your step-count data. We ask that you do not use any content on the Fitbit app other than step count tracking. At the end of the study, we will extract the Fitbit data using the Fitbit app. These data will be stored on VABox before being transferred immediately behind the VA firewall. VABox is a desktop application that keeps all users files safe and secure in the cloud.
- At the end of enrollment, we will reset the Fitbit to the factory settings. You can keep the Fitbit.
- At the end of the study, if we provided you an iPad, you will be asked to return the iPad using a prepaid mailer. If you withdraw prior to this visit, you will be asked to return the study-issued iPad using a provided prepaid mailer. It will be reset to factory settings.
- You will be asked to download VA Share My Health Data app on your smartphone or iPad and share Fitbit data with the study PI (Dr. Bamonti). The Share My Health Data app allows Veterans to view data from health tracking devices all in one place and share it with VA care teams. We will use the app to sync your Fitbit app so that the study therapist can view your weekly step counts and discuss them with you during the study sessions. Study staff will only view your step count data during study enrollment. If you cannot do this or decide you do not wish to, you can still participate in the study.
- To log-in to VA Share My Health Data app you need Login.gov credentials. You may already have this. If not, we will ask you to create an account. Instructions for creating this account can be found online at Create your Login.gov account | Login.gov. If you cannot do this or decide you do not wish to, you can still participate in the study.

What is Step-CBT? Step-CBT stands for Step + Cognitive Behavioral Therapy. Cognitive behavioral therapy (CBT) is an existing mental health intervention that treats conditions such as depression and anxiety. It involves learning about how your thoughts (what you tell yourself), behaviors (what you do), and your emotions (what you feel) impact your depression and/or anxiety. We have adapted CBT to include a focus on how COPD impacts your thoughts, behaviors, and emotions. You will work with either the PI, a licensed clinical psychologist, or a psychology doctoral intern under the supervision of the PI, on a weekly basis where you will work collaboratively to learn about how your behavior and thought patterns

impact your mood. We will also address the "step" or physical activity in your life to address low physical activity. We have combined a walking intervention with CBT, thus Step-CBT. You will be asked to attend weekly appointments with the interventionist over VVC or Cisco Webex, as well as complete practice assignments to help you increase your physical activity and improve your mood. These practice assignments focus on individual goals and you will be asked to write down if you meet your goals.

VVC is a secure virtual platform used in the VA Healthcare System to interact with your providers from your home. You will be provided with a manual containing all the content for each session for you to follow along. In addition, you will be asked to log your step counts every day on a paper and pencil log and note any barriers that you encounter day-to-day. If VVC is down or if you prefer Webex, the sessions will be held using Cisco Webex. Although Cisco Webex is secure and fully VA-authorized, it is not a VA site and is not controlled, monitored, or managed by the VA.

Here's a sample session: We will check-in about your walking goals and create new goals; we will focus on scheduling pleasant events during the week, and you will receive education on the connection between mood and pleasant events. We will problem solve if you run into barriers related to walking goals and therapy assignments. Each session lasts 60 minutes.

Prior to beginning Step-CBT, you will be asked to:

- Return the ActiGraph and ActiGraph Wear Time Log to us using the provided prepaid mailer.
- You will be called by study staff to schedule an orientation session with the study staff introducing Step-CBT. This appointment will take place using VVC or Cisco Webex.
- Receive the paper copy of the Step-CBT Veteran treatment manual by mail.
- Keep the Fitbit pedometer and wear for the remainder of the study.
- You will be asked to wear the Actigraph for 7 days following Session 8 of Step-CBT. Do not worry about remembering these dates, study staff will provide you with reminders by phone and mail.
- Complete the Step Count Log every week during your enrollment. The Log asks you to record your daily step count and whether you achieved your daily SMART goal.
- Complete assessment of mental health following completion of Session 4 (Week 6) with study staff over the telephone or using VVC or Cisco Webex.

- Participate in a final study session using VVC or Cisco Webex where you will repeat the repeated chair stand test and questionnaires, and return the ActiGraph using a pre-paid mailer.

At all times during the study, you can contact us at [redacted] (anytime) or [redacted] (8:30am-4:30pm EST) if you have any questions or wish to report an adverse event. We will contact you for study visits using the phone number you provided.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Attend your study appointment as scheduled. If you are going to miss an appointment, please contact the PI or research staff to reschedule as soon as you know you will miss the appointment.

Optional: If agreeable, Step-CBT sessions may be audio recorded for review by the PI and research staff. The audio recording will not collect any personally identifiable information and will be stored securely and confidentially. This is voluntary and will not affect your participation in the research study.

____ Initial here to opt-in to the audio recorded interview.

Wear the Fitbit pedometer for the entirety of the time you are in the study. Upon completion of the study, the Fitbit pedometer will be yours to keep. Wear the ActiGraph during the instructed timepoints and return using the provided prepaid envelope. Inform the PI or research staff if there are any issues with the Fitbit pedometer or ActiGraph.

If provided a study-issued iPad, you are expected to only use the iPad for the research study (i.e., downloading and using the Fitbit app, attending Step-CBT sessions). Do not enter or store any personal information on the device. Inform research staff if there are any issues with the iPad. Study-issued iPads are tracked by study staff. You will return the iPad by prepaid mailer following the final study session or if you withdraw prior to the final session. Compensation for the final study visit will be withheld until the issued iPad is returned. iPads will be returned to factory settings upon return.

Complete your questionnaires as instructed to the best of your comfort and ability. Ask questions to study staff as you think of them.

While participating in this research study, do not take part in any other intervention research project for physical activity or mental health, new exercise program, or begin psychotherapy for mental health without approval from the investigators. This is to protect you from possible injury from things such as additional physical activity. Taking part in other intervention research studies for physical activity or mental health, a new exercise program, or initiating psychotherapy for mental health without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any research study has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

Physical Activity Monitors: There are no known risks to wearing the Fitbit pedometer around the wrist. You may adjust the band of the Fitbit pedometer to suit your comfort level. The ActiGraph is an FDA-approved medical device and is worn around the ankle with a soft Velcro strap; there are no known risks associated with wearing the ActiGraph. You will be allowed opportunities to rest.

Questionnaires: Content is on topics not generally considered controversial or likely to produce psychological distress. It is possible that some questions on the questionnaires may make you feel uncomfortable. You do not need to answer these questions. Frequent breaks will be provided. You will be provided the opportunity to complete questionnaires over multiple days if inconvenienced or fatigued. Your answers will be entered into VA REDCap, which has a secure data storage platform. Only your unique study identifier – not your name – will be recorded with the answers provided on these questionnaires.

Cognitive Screening: You will participate in a brief testing of your thinking and memory. The purpose of the cognitive screening is to provide an estimate of your thinking and memory but it cannot be used to diagnose you with a medical condition. You do not have to participate in the screening if you are uncomfortable. However, if you choose not to take part in the cognitive testing, you will be ineligible for participating in the study.

Repeated Chair Stand: You will undergo a measure of physical functioning that involves getting up and down from a chair more than once. The test takes < 5 minutes in total. You do not have to participate in this test if you are uncomfortable. It is possible this test can cause temporarily

shortness of breath or dizziness. You can stop and rest at any time. There is a risk of falling. The evaluator is trained in administering this test safely.

Fitbit Pedometer-based Walking Program: The proposed walking intervention presents minimal risk if you have been deemed medically stable by your usual healthcare provider. Potential risks related to walking and exercise, and progression of exercise include:

- Risks related to Increasing Physical Activity: You may experience leg pain, foot pain, back pain, lightheadedness and/or dizziness when increasing your physical activity.
- Risks related to Breathing: You may experience shortness of breath while walking. This could be a sign of heart problems, but in most cases, it is likely to be indicative of low fitness or reflect your lung problem.
- Risks related to Musculoskeletal Injury: Walking programs are much less likely to result in minor musculoskeletal injury than more vigorous exercise programs. However, musculoskeletal injury can occur even in walking programs. There is a risk of falling.
- Risks related to Cardiovascular Disease: You may have at least one cardiovascular disease risk factor, and thus be at increased risk of experiencing chest pain or a heart attack.
- Risks related to Chronic Pain: Regular exercise, such as walking, is a generally recommended therapy for people with chronic pain. However, when starting a walking program, individuals with chronic pain may experience temporary muscle soreness or stiffness or it may worsen an underlying pain condition.
- Risks related to Diabetes: You may have diabetes. A physical activity program is an important part of managing your diabetes. However, for people with diabetes who start a walking program, there is a risk of having episodes of low blood sugar after exercising or problems with ulcers or sores on the feet.

  Risks related to Blood Pressure Control: Starting an exercise program may lower an individual's blood pressure. If you take medication to lower your blood pressure you may need to have your blood pressure medication adjusted as you progress in the program. Similarly, if you have poorly controlled blood pressure you may experience even higher blood pressures as you progress in the program.
- Risks related to Hydration: If you are on fluid restriction or diuretics you may have trouble hydrating sufficiently when walking in hot weather.

VVC Intervention: VVC is a secure, private virtual medical appointment, used in routine care across VHA. You may have family in your home who can overhear your appointment causing risk to privacy and confidentiality. As such, you will be asked to find a private space within your home. If this is not possible, you can choose, at any point, to discontinue the study session if you feel uncomfortable to participate due to privacy concerns.

Cisco Webex: Cisco Webex is offered as a back-up to VVC. Although Cisco Webex is secure and fully VA-authorized, it is not a VA site and is not controlled, monitored, or managed by the VA. There is a small chance that a person not connected with the study may gain access to your virtual study visit. There is a risk of loss of privacy if you choose to hold your Cisco Webex virtual study session in public.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. You will be asked to report any adverse event while participating in this research study such as a change in your clinical condition, change in medications, and/or urgent care visits, emergency room visits, or hospitalizations. Study staff will request hospital discharge summaries, medication records, chest X-ray reports, CT scan reports, and any additional information using the VA Form 10-212 following a report of any adverse event.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: We will store your information on a secured network behind the VA Boston firewalls and in locked cabinets in locked offices at VA Boston (detailed below).

To protect your confidentiality, we will use a unique study code instead of your name whenever possible to identify your information (e.g., your questionnaires). One master list links your study

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ID with your name and other identifiable information. This master list is located on a secured network behind the VA Boston firewalls.

Your information and questionnaire responses will be entered and stored on secured networks behind the VA Boston firewalls and VA Research REDCap server. Study computer files are password-protected. All paper records are kept in locked cabinets in locked offices at VA Boston. Only research staff have access to these files and document.

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule.

To comply with state laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

If you report a health problem for which you received medical care, study staff may request medical records from institutions outside the VA in order to obtain the details of your medical care. We will use your personal information in order to request the medical records. By signing this informed consent document, you authorize research study staff to use your personal information to request medical records from institutions outside the VA for health problems you have reported to research study staff.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

An unsigned copy of this consent form will be posted on clinicaltrials.gov after all study participants have completed the study.

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

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Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. While it is not the intent of this study, other information such as HIV status, drug, alcohol, or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary, or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: VA Rehabilitation Research & Development, the Fiscal Office of the VA Boston Healthcare System, the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must ask a member of the research team to give you a form to revoke the authorization. If you review this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Patricia Bamonti, Ph.D.** and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

You will be compensated up to $100 in total for your time and effort taking part in this study. You will receive $50 by debit card or direct deposit for completing baseline assessments. You will receive another $50 by debit card or direct deposit for completing final study assessments (end of the study). If you decide to withdraw from the research study before its completion, you will receive compensation up to the last study visit you have completed. Compensation will be withheld if study-issued iPads are not returned following the final study visit.

If Receiving Payment by Debit Card: You consent to the release of personally identifying information including your name, address, social security number to the VA so that we may provide compensation to you. You can expect to receive a debit card within 2-6 weeks.

If Receiving Payment by Direct Deposit: You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You will receive payment within 7 to 10 days.

If payment is made to you by the VA (whether by VA issued debit card or direct deposit), an IRS Form 1099 will be generated regardless of the amount you are paid. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

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If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: **Dr. Patricia Bamonti** at [redacted]
AFTER HOURS: **Dr. Patricia Bamonti** at [redacted]

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee, refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations.

You can withdraw from the study at any time without any penalty, loss of rights, or loss of VA or other benefits you have a right to receive. To do this, call Dr. Bamonti at [redacted] or [redacted]

If you withdraw, the research team may continue to use or disclose the information that had already been collected before you withdrew, which the research team has relied upon for the research. The study team will not continue to collect information from you after you withdraw from the study.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You may be withdrawn from the study by the PI if the combined number of cancellations and no-shows exceeds a total of 5, with no more than 3 of these cancellations or no-shows occurring directly after another. This intervention must be completed in no more than 18 weeks.

You may be withdrawn from the study by the PI if during you participation in this study you become verbally abusive or otherwise act inappropriately toward study staff.

You may be withdrawn from the study by the PI if during the study visit you show evidence of significant distress or intent to harm yourself or others. The PI will ensure adequate follow up/ referral if they feel it is necessary.

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In the unlikely event that this occurs, it will be managed through routine practices, such as escorting you to the Urgent Care clinic/Emergency Department, calling for additional assistance from hospital staff, or calling the VA police. If you experience a medical problem that prevents walking and exercise, you will be temporarily suspended from the study and will resume when at your normal level of functioning.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any medical questions about this research study, you can call **Dr. Patricia M. Bamonti** at [redacted] anytime or [redacted] during normal working hours.

If you have any general questions about this research study, you can call **Dr. Patricia M. Bamonti** at [redacted] anytime or [redacted] during normal working hours.

If you have any medical problems that might be related to this study, you can call **Dr. Patricia M. Bamonti** at [redacted] anytime or [redacted] during normal working hours. If you have any mental health concerns that might be related to this study, you can call **Dr. Patricia M. Bamonti** at [redacted] anytime or [redacted] during normal working hours.

If you have questions about your rights as a study participant or any complaints, concerns or suggestions about this study, you may contact **the Institutional Review Board** at [redacted]. The Institutional Review Board is responsible for overseeing the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in this study.

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Participant Name: _____ Date: _____

Title of Study: **The Development of an Integrated Physical Activity and Mental Health Intervention for Veterans with Chronic Obstructive Pulmonary Disease (COPD), Emotion Distress, and Low Physical Activity: Feasibility of Step-CBT in Veterans with COPD and Emotional Distress (Study 3)**

Principal Investigator: **Patricia M. Bamonti, PhD** VA Facility: **VA Boston Healthcare System**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Patricia Bamonti and/or a Research Assistant has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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