Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: The Impact of a Home-Based Pulmonary Telerehabilitation Program on Muscle Functionand Quality of Life in Chronic Obstructive Pulmonary Disease_____

Principal Investigator: Jessica Bon Field, MD, MS_____ VAMC: Pittsburgh (646)

LAY TITLE: THE IMPACT OF A HOME-BASED PULMONARY TELEREHABILITATION PROGRAM ON MUSCLE FUNCTION AND QUALITY OF LIFE IN COPD

KEY ELEMENTS:

This is a research study to find out if a home- based pulmonary telerehabilitation program, which is an exercise program that is performed at home while being guided and monitored by an exercise physiologist using video conferencing software, can improve physical activity levels, exercise endurance, muscle strength, and quality of life. Your participation in this study is voluntary.

When you are enrolled in this study, you will be assigned either to a group that participates in pulmonary telerehabilitation sessions after hospital discharge in addition to post-hospital standard (usual) care or to a group that receives standard care alone. You will have tests, exams and procedures that are part of your standard care and for study purposes prior to discharge from the hospital.

If you are assigned to the pulmonary telerehabilitation group, you will participate in 3 pulmonary telerehabilitation sessions a week for 8 weeks following hospital discharge. Each session will last approximately 75-90 minutes and will begin 1-6 weeks after hospital discharge.

You will be asked to return 10-18 weeks following hospital discharge to complete approximately 4 hours of additional testing. You will also be asked to wear a pedometer every day following hospital discharge to measure activity.

There are risks to this study that are described in this document. Some risks include slight soreness in muscles and/or breathlessness due to the effort involved during the assessment and/or the intervention exercise.

If you do not participate in this study, alternate treatments would include participation in another exercise program or pulmonary rehabilitation. You may choose not to exercise at all after hospital discharge.

If you are interested in learning more about this study, please continue reading below.

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STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call study staff at 412-360-2127 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Field during the daytime 412 360-6146 or the operator at 1-866-785-9015 during after-hours or on the weekends. Tell the operator that you are a research subject from the Pittsburgh VA in the Impact of a Home-Based Pulmonary Telerehabilitation Program on Muscle Function and Quality of Life in COPD Study and need to speak with Dr. Field. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Field or another person listed below who will call you back. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

Principal Investigator
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STUDY SPONSOR:
VA Rehabilitation Science Research and Development. Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY:
The purpose of this research study is to evaluate the impact of a pulmonary telerehabilitation program after hospital discharge on changes in physical activity levels, exercise endurance, muscle strength, and quality of life. Chronic obstructive pulmonary disease (COPD) is common in veterans who smoke or who have a history of smoking. Acute exacerbations, or flare-ups, of COPD can cause muscle weakness,

decrease exercise tolerance, and lead to worse quality of life. Pulmonary rehabilitation, an exercise program that includes both endurance and strength training exercises, has been shown to improve muscle strength and endurance and quality of life after an acute exacerbation of COPD. However, lack of rehabilitation facilities nearby and/or transportation issues often prevent patients from enrolling in pulmonary rehabilitation programs. This project will assess the feasibility and impact of a home-based, pulmonary telerehabilitation program in veterans with COPD following an acute exacerbation of their lung disease. Participants will be randomly assigned to either an eight-week, three sessions per week home-based pulmonary telerehabilitation program via videoconferencing that will include both endurance and strength training exercises or to the standard care that would typically occur following discharge from the hospital after an acute exacerbation of COPD.

Thirty-eight male and female veterans at the VA Pittsburgh Healthcare System (VAPHS), University Drive Campus will be enrolled in this study.

You are being asked to participate in this research study because you are a male or female veteran between the ages of 40-80, have been diagnosed with moderate or severe COPD, and are currently hospitalized for an acute exacerbation (flare) of your COPD. You are also being invited to participate in this study because you did not require mechanical ventilation during this hospital admission, you do not have unstable cardiac or neurologic disease, you do not have a medical condition that would not allow you to participate safely in an exercise program, you have not participated in a pulmonary rehabilitation program within the past 6 months and have elected to participate in this study prior to enrolling into a facility-based pulmonary rehabilitation program, you are not pregnant or are pregnant but do not have any restrictions placed on activity or exercise by your doctor, and you are not currently enrolled in another greater than minimal risk 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 Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:

Subject Name: _____ Last 4 SSN: _____ Date: _____

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Principal Investigator: Jessica Bon Field, MD, MS VAMC: Pittsburgh (646)

You will go over this consent form with the study coordinator/investigator, will be asked to read and sign it, and then will be randomly assigned to participate in the pulmonary telerehabilitation program or to standard care, which is the care that you would normally receive from you doctors, following hospital discharge. The study coordinator/investigator will then ask you some basic demographic and clinical questions. Both the pulmonary telerehabilitation and usual care groups will undergo baseline questionnaires, sit-to-stand testing, muscle strength testing, and Six Minute Walk testing prior to discharge as described below. Participants assigned to the pulmonary telerehabilitation group will also participate in one to three bedside exercise sessions with an exercise physiologist/study coordinator prior to discharge.

If you are assigned to the pulmonary telerehabilitation group you will participate in an intention to treat model of an 8-week, 3 sessions per week exercise program via videoconferencing with an exercise physiologist as described below.

You will be asked to return to the VAPHS University Drive Campus 10-18 weeks following discharge to repeat questionnaires, sit-to-stand testing, muscle strength testing, and shuttle walk testing. If you are assigned to the pulmonary telerehabilitation group, you will also be asked to complete a survey about the exercise program at this follow up visit.

You will be enrolled in the VAPHS telehealth monitoring program and will be provided with a blood pressure cuff, pulse oximeter, and scale to measure daily blood pressure, pulse, oxygen saturation, and weight.

You will receive a Pedometer at hospital discharge. You will wear the pedometer every day following hospital discharge to track your physical activity. Study staff will provide you with a pedometer diary for you to record your steps each day. Study staff will call you weekly to document your pedometer activity.

I. BASELINE TESTING (In-hospital testing prior to discharge)

Prior to conducting any study procedures, the study coordinator/investigator will go over this consent form with you and you will be asked to read and sign it. After signing the consent form and being

assigned to either the pulmonary telerehabilitation or usual care group, you will be asked questions about yourself and your family (demographics, past and present illnesses, medications, etc.). You will then be asked to complete one breathing questionnaire and one quality of life questionnaire. During your hospitalization prior to discharge, you will be asked to perform one sit-to-stand test and one six minute walk test. The six-minute walk will be measured in all subjects. This test will be performed indoors, along a flat straight or rectangular, enclosed corridor with a hard surface. You will walk for 6 minutes while on your exercise oxygen prescription and will rate your shortness of breath and muscle fatigue before the test and after the test using the modified Borg scale. The Borg scale is numbered 0 through 10. Zero represents rest and normal breathing while 10 represent when you are breathing and working as hard as you can. We will also measure your vital signs and blood oxygen saturation levels before and after this test. The six-minute walk test should take about 30 minutes to complete.
You will also complete a measurement of your hand grip strength.

Optional Testing: Approximately one week after hospital discharge you will be asked to return to the VA Research Center to complete the quadriceps muscle strength test, which is an optional test.

You will also be given a pedometer to be worn every day to track your physical activity. You will be asked to keep track of your steps daily on the pedometer diary provided to you by study staff. Study staff will call you weekly and ask you to report for the number of steps taken that week.

All of these study procedures will last about 4 hours in total. All will be conducted at the University Drive Division of the VAPHS.

I. PULMONARY TELEREHABILITATION INTERVENTION GROUP

If you are assigned to the pulmonary telerehabilitation intervention group, you will participate in an intent to treat 8-week, 3 sessions per week, home-based pulmonary telerehabilitation program that will include both lower or upper extremity exercises with a cycle ergometer (a portable, folding pedal exerciser that can be placed on the floor for leg pedaling or, if necessary, on the table for arm pedaling, and that allows you to change the resistance level) and upper and lower extremity strength training with resistance bands. An exercise physiologist/study coordinator will meet with you for 1 to 3 bedside exercise sessions prior to

hospital discharge to teach you how to use the equipment and how to perform the exercises, to create an exercise plan for your home exercises, and to make sure that you are doing the exercises safely and do not need to wear supplemental oxygen with exercise. You will be asked about shortness of breath and leg fatigue during the exercise sessions.

If you are assigned to the pulmonary telerehabilitation group, you will be provided with a cycle ergometer and a set of exercise resistance bands prior to hospital discharge. This equipment will be yours to keep. The VAPHS will supply you with a tablet with data plan that includes video conferencing software for the pulmonary telerehabilitation sessions. You will return this tablet at the end of the study. Physical activity will be measured using a pedometer every day after hospital discharge. You are asked to wear the pedometer every day and record your daily steps on the pedometer diary provided to you by the study staff. We will contact you by telephone weekly to document your pedometer activity. You will also be enrolled in the VAPHS telehealth program. The telehealth program will provide you with a blood pressure cuff, pulse oximeter, and scale and will ask you to take daily measurements of your pulse, blood pressure, oxygen saturation, and weight. Prior to discharge from the hospital, you will undergo all baseline testing (questionnaires, sit-to-stand testing, six-minute walk testing, and hand grip strength. Quadriceps muscle strength testing will be optional for patients willing to travel to the Research Center for this additional leg strength measurements approximately one week following discharge.

Within 1-6 weeks of hospital discharge, if you are assigned to the pulmonary telerehabilitation group, you will begin pulmonary telerehabilitation sessions via one-to-one video conferencing with an exercise physiologist/study coordinator. The exercise physiologist will be located at VAPHS during these sessions and will communicate with you through the video conferencing software. These sessions will occur 3 times a week and will last for approximately 75-90 minutes each. The sessions will include: (1) A brief pre-exercise interview where the exercise physiologist will ask you about symptoms and ask you to take your vital signs (pulse rate, blood pressure, and oxygen saturation); (2) a warm-up period consisting of upper and lower extremity stretching exercises; (3) 20-40 minutes of lower-limb cycle ergometry (or upper-limb cycle ergometry if necessary), (4) upper and lower extremity strength training with resistance bands; (5) a post-exercise debriefing interview where the exercise physiologist will ask you about symptoms and have you recheck your vital signs. You will be asked about symptoms of shortness of

breath and leg fatigue while you are exercising. Study participants assigned to the pulmonary telerehabilitation group will also participate in a once monthly online support group via telephone conferencing with a study team member. This is an optional support group.

I. USUAL CARE GROUP

If you are assigned to the usual, or standard, care group, you will perform all baseline testing (questionnaires, sit-to-stand testing, six minute walk testing, hand grip and optional quadriceps muscle strength training) during your hospitalization. You will also meet with an exercise physiologist/study coordinator to discuss the importance of exercise in COPD prior to discharge

II. FOLLOW-UP TESTING

You will be asked to return approximately 10-18 weeks following hospital discharge for follow-up testing. Testing will include repeating the breathing and quality of life questionnaires, a sit-to-stand test, one six minute walk test, and measurement of hand grip strength. If you opted to have your quadriceps muscle strength tested at baseline, we will repeat this measure at the follow-up visit as well. If you were assigned to the pulmonary telerehabilitation group, you will also be asked to complete a survey that will ask your opinions about the pulmonary telerehabilitation program. You will also be asked to return your tablet at this time.

Detailed Study Procedures:

A. Questionnaires (Research Procedures)

The **breathing questionnaire** is known as the St. George's Respiratory Questionnaire (SGRQ). This is a paper and pencil questionnaire that inquires about respiratory symptoms, quality of life, and shortness of breath. The breathing questionnaire will take approximately 10 minutes to complete.

The **quality of life questionnaire** is known as the SF-36. The SF-36 is a paper and pencil, 36 question questionnaire that inquires about your physical and mental health. The SF-36 questionnaire will take approximately 10 minutes to complete.

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The **pulmonary telerehabilitation program** survey will be given to all study participants assigned to the pulmonary telerehabilitation group. This survey will ask your opinions about the pulmonary telerehabilitation program and will take approximately ten minutes to complete.

B. Sit-to-stand testing (Research Procedure) is a simple measure of exercise capacity and leg strength. You will be asked to stand at full leg extension from a sitting position at your own pace as often as possible during a one-minute testing interval. You may stop at any time during the one-minute interval if necessary.
An armless chair will be used for testing and you will be asked to fold your arms across your chest during the test. This test will take approximately one minute.

C. The six-minute walk will be measured in all subjects. This test will be performed indoors, along a flat straight or rectangular, enclosed corridor with a hard surface. You will walk for 6 minutes while on your exercise oxygen prescription and will rate your shortness of breath and muscle fatigue before the test and after the test using the modified Borg scale. The Borg scale is numbered 0 through 10. Zero represents rest and normal breathing while 10 represent when you are breathing and working as hard as you can. We will also measure your vital signs and blood oxygen saturation levels before and after this test. The six-minute walk test should take about 30 minutes to complete.

D. Measurement of hand grip and quadriceps strength (Research Procedure) will be performed by the use of a handheld dynamometer, a device that measures muscle force. You will be asked to close your hand around the handheld dynamometer and squeeze. If you are willing to return to the VA approximately one-week post discharge to complete the quadriceps strength test, you will be asked to straighten your leg against the leg dynamometer to measure muscle force. This test will be optional. You will be asked to repeat these maneuvers several times each.

E. Pulse oximetry (Standard of Care Procedure) is a simple non-invasive method of measuring blood oxygen levels. The pulse oximeter utilizes a probe that is placed on your finger or attached to your ear lobe. This probe is connected to a computerized unit that is able to measure blood oxygen levels. Your blood oxygen levels will be tested on room air and on your current resting oxygen prescription if applicable. During this test, we may see that your oxygen level is low (below 90% saturation) while on

room air or on your current resting oxygen prescription. If this happens, we will notify your primary care doctor of the test results and refer you to the home oxygen program for further evaluation of your supplemental oxygen requirements. Pulse oximetry will be monitored during both the incremental and endurance shuttle walk testing and during the bedside pulmonary rehabilitation sessions in study participants assigned to the pulmonary telerehabilitation group.

F. Pedometer You will also be asked to wear a Pedometer following hospital discharge to track your physical activity. You will be asked to wear the pedometer every day and to record your total steps at the end of every day on the pedometer diary provided to you by study staff at the time of discharge. We will contact you by telephone weekly to document your pedometer activity.

All study procedures will be conducted at the University Drive Division of the VA Pittsburgh Healthcare System.

Your participation in this study is for approximately 10-18 weeks unless you choose to withdraw your consent or are unable to return to the University Drive Division of the VA Pittsburgh Healthcare System for the follow-up study visit.

Any electronic or hard/paper copies of information collected about you will be stored in a secured location. Only those individuals who are authorized to review your information will have access to it.

RISKS AND BENEFITS:
Any procedure has possible risks and benefits. The procedures in this study may cause all, some, or none of the risks listed.

Measurement of hand grip, quadriceps strength (optional), and sit-to-stand testing
These tests are considered to carry a low risk of harm but may occasionally cause slight soreness in muscles and/or breathlessness due to the effort involved. Shortness of breath can be expected to occur (in more than 25% of people) during and for a few minutes after testing.

Six Minute Walk testing

This test is considered to carry a low risk of harm but may occasionally cause slight soreness in muscles and/or breathlessness due to the effort involved, However, shortness of breath will be likely and expected to occur (in more than 25% of people) during and for a few minutes after the test. All staff is fully trained in basic CPR and physician supervision is provided throughout the test.

Questionnaires
Completing the questionnaires may make you tired. It is possible that some of the questions may make you feel embarrassed. If any question makes you feel uncomfortable, you do not have to answer it.

Participating in the pulmonary telerehabilitation intervention
Participation in the pulmonary telerehabilitation intervention may occasionally cause slight soreness in muscles and/or breathlessness due to the effort involved. Maximal exercise testing is associated with a 1 in 10,000 chance of significant untoward outcome (e.g., heart attack, abnormal heart rhythm), including the possibility of death in patients with known cardiovascular disease. All exercise performed as part of this study will be at a much lower work capacity and you will be screened prior to participation to lower the overall risk of a medical event. You will also engage in a minimum of one to two bedside pulmonary rehabilitation sessions prior to hospital discharge. If you are felt not to be able to safely participate in a home exercise program based on observation during these sessions, you will be excluded from participating in the study.

Pedometer : Wearing this device may be an inconvenience.

As with any experimental procedure, there may be adverse events or side effects that are currently unknown. These unknown risks could be permanent, severe, or even life threatening. Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside the VA.

Risks to Pregnancy
If you are pregnant, there should not be any additional risks to you or your fetus from participating in this study. However, if you doctor has placed restrictions on your activity or has advised you not to exercise during pregnancy, then you should not participate in this study.

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You may also experience some side effects related to the procedures/medications/treatments you receive that are not part of the research but are considered standard of care for your condition. A description of these side effects should have been provided to you by your physician. If you have not received information regarding these side effects, please contact your physician.

Potential Benefits: If you are assigned to the pulmonary telerehabilitation group, you will have the opportunity to participate in a home-based exercise program that may have a positive impact on muscle strength, exercise endurance, and quality of life.

You may benefit from participating in this study. Direct benefits may include: decreased shortness of breath with activity, increased muscle strength, increased exercise tolerance.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options.

NEW FINDINGS:
You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

INVESTIGATOR INITIATED WITHDRAWAL:
The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW:
Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Please contact Dr. Field or one of the study team members at the phone numbers listed on the first page of this consent form as soon as you decide to withdraw from this research study. To formally withdraw your

consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. You must also fill out a revocation of authorization for use and release of individually identifiable information for VHA research form to withdraw from this study. This form can be obtained from the study coordinator or investigators at any time.

Your doctor may also be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor.

Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

If you are assigned to the pulmonary telerehabilitation group and choose not to continue the exercise sessions, you will be withdrawn from the study

MEDICAL TREATMENT:
In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION:
If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If

compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS:
You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

As a token of our appreciation for your time and invaluable contribution to this study, you will be compensated with a payment of $50 after completion of all baseline, in-hospital testing and with a payment
of an additional $100 after completion of all follow-up testing. Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel have provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose. If you are a Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

Since the payments made via the EFT go through multiple departments, the time taken for you to actually receive the money may vary. Please contact one of the study coordinators if you have any problems with the EFT payments.

RECORD RETENTION:

Subject Name: _____ Last 4 SSN: _____ Date: _____

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Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA 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 HIPAA 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. They may also collect other information including:

Information from your Health Records such as diagnoses, progress notes, medications, lab or radiology findings.
Specific information concerning HIV

Demographic Information (Last, First, Middle Initial); Subject SSN (last 4 only); date of birth.

Questionnaire, Survey, and/or Subject Diary

A progress note stating you are participating in this study will be placed within your medical record.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress.

Others may include VA Institutional Review Board (IRB) who will monitor the study,

Study Sponsor and Authorized VA Rehabilitation Research and Development personnel,

Compliance and Safety Monitors Data safety monitoring board (DSMB)

The research team may also need to disclose your health information and the information it collects to others as part of the study progress.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be known.

Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Any copies that contain information that could be used to identify you (such as your name, address, date of birth, etc.) will be stored separately from any information that does not contain identifiers. Only those individuals who are authorized to review your information will have access to it. Any digital files containing identifying information will be password protected and all information will be stored on a secure VA shared drive accessible by the study team members only.

Future Use: Your information collected as part of research, even if identifiers are removed, will not be used or distributed for future research studies.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the

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Release of Information Office receives it. If you revoke 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.

Principal Investigator
Jessica Bon Field, MD, MS
VA Pittsburgh Healthcare System
University Drive C (111S-U)
Pittsburgh, PA 15240
(412) 360-6823

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.

RESEARCH SUBJECTS' RIGHTS:
You have read or have had read to you all of the above and any applicable consent addenda. Dr. Field or her authorized representative has explained the study and any optional study components to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You understand that these Research Subjects' Rights also apply to any optional study components to which you have agreed to participate. You will receive a copy of this signed consent form.

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If you have any questions about your rights as a participant in this study or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

Version Date October 5, 2021 v 1.5