Date: Wednesday, July 28, 2021 11:41:19 AM
ID: Pro00002952 View: 0.0 Type of Submission Entry

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 * **Study Name:**
The impact of a home-based pulmonary telerehabilitation program on muscle function and quality of life following acute exacerbations of chronic obstructive pulmonary disease

2.0 * **Brief Description (using layman's terms) - 500 words or less:**
COPD impacts a significant proportion of the veteran population. Acute exacerbations, or flare-ups, of COPD are associated with impaired muscle function and worse quality of life. Pulmonary rehabilitation, a formal exercise program for patients with lung disease that includes both endurance and strength training exercises, has been shown to improve muscle function and quality of life after an acute exacerbation of COPD. However, lack of geographically accessible rehabilitation facilities and/or transportation issues are often barriers to pulmonary rehabilitation attendance in the veteran population. This study will assess the feasibility and impact of an intention to treat, eight-week, three sessions per week, home-based, pulmonary telerehabilitation program in veterans with COPD following hospitalization for an acute exacerbation of their lung disease. We will measure adherence and satisfaction with the program and muscle strength, physical activity, quality of life, and exercise tolerance pre and post-intervention in veterans randomized to the pulmonary telerehabilitation arm versus veterans randomized to the control arm who do not participate in pulmonary rehabilitation.

3.0 * **Is this research study a Greater than Minimal Risk Clinical Trial?** (●) **Yes** ( ) No

4.0 * **Is this study a Greater than Minimal Risk Comparative Effectiveness research?** ( ) Yes (●) **No**

5.0 * **Principal Investigator:**
Jessica Field

5.1 * **VA hours per week the PI is devoted to project:**
4

5.2 * **Is the PI working with ionizing radiation?** ( ) Yes (●) **No**

5.3 * **Is the PI working with biological hazards?** ( ) Yes (●) **No**

5.4 * **Is the PI shipping biological hazards?** ( ) Yes (●) **No**

A completed and signed Research Financial Conflict of Interest Statement is required for all investigators (including Principal Investigators, Co-Principal Investigators, and Co-Investigators) listed on the study application. **Financial Conflict of Interest Form-Nov. 2013**

5.5 **Upload Financial Conflict of Interest Statement:**
SPiRE_Field_FCOI OGE Form 450 Fillable PDF-VA 3-19-14.pdf(0.01)

7.0 **Type of Submission:**

	Description
◉	**This is a new study. This has not previously been submitted to the IRB.**
○	This is a new paper conversion. This study has been previously approved by the IRB.

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

ID: Pro00002952 View: 1.0 Study Identification Information

Study Identification Information (Continued)

1.0

*** Do you certify that all research staff administering informed consent are knowledgeable about the study?**

yes

2.0

*** To the best of your knowledge do you, or any member of your research staff, have any potential, actual or perceived conflict of interest of a professional or personal nature that may affect any aspect of the research, including, but not limited to, the review and/or conduct of this study?**

○ Yes ◉ **No**

If yes, provide a description, including name of study team member with conflict:

3.0 *** Qualifications of the Investigators:**

Jessica Bon Field, MD, MS is an Associate Professor of Medicine in the Division of Pulmonary, Allergy and Critical Care Medicine at the University of Pittsburgh and a Staff Physician at the VAPHS. Dr. Field engages in clinical and translational COPD research with a focus on musculoskeletal comorbidities.

Daniel E. Forman is a Professor of Medicine in the Division of Geriatrics and Division of Cardiology at the University of Pittsburgh and a staff physician at the VAPHS. Dr. Forman is studying the effects of different exercise training regimens on skeletal muscle morphology, gene expression and function capacity.

ID: Pro00002952 View: 1.2 VA Involvement

VA Involvement

1.0

Does the proposed research involve any of the following?:

	Name
☑	**VA Funding**
☐	VA Personnel Funded Effort
☑	**VA Patients or their Private Health Information**
☐	Other VA Resources: Central IRB

- [x] **Other VA Resources: VA Equipment**
- [x] **Other VA Resources: VA Property (Including space leased to, or used by VA)**
- [ ] Other VA Resources: VA Databases
- [ ] None of the Above apply to this research

ID: Pro00002952 View: 1.3 Study Funding Information

Study Funding Information

1.0 * **Funding Sources:**

	Funding Source	(Other)	Code
View	Rehabilitation R&D (Prog 822)		9022

2.0 **Upload Grant Application, if applicable (If NIH, VA, voluntary agency, must upload):**

Name	Modified Date
Egrant.pdf	2/4/2019 2:43 PM

ID: Pro00002952 View: 1.4 Resources

1.0

*** Do you currently have adequate resources (e.g., staff, physical space, information technology, etc.) to protect the safety of participants, staff, and the confidentiality of subjects' data during the conduct of this study?**

(•) **Yes** ( ) No

If yes, include a listing of the VAPHS resources that will be used for this study and are necessary to protect participants.

We have the adequate number of qualified staff to conduct this study. Each participant will be enrolled in home telehealth and home telehealth equipment that includes a blood pressure cuff and pulse oximeter to allow monitoring of vital signs during the pulmonary telerehabilitation intervention will be provided to each participant (both control group and intervention group). We will use Dr. Daniel Forman's (co-investigator) Keiser leg press to measure lower extremity strength. Activity monitors, cycle ergometers, and resistance bands have been budgeted for and will be purchased through grant funding.

If no, please describe the resources that will be needed and explain how the resources will be obtained before the study is initiated:

2.0 * **VAPHS requires that either the PI or co-PI have a *physical presence* at VAPHS. Please describe the role the PI and/or co-PI have at VAPHS with respect to clinical responsibilities or in relation to other research activities.**

Dr. Field (PI) has a 5/8th appointment (3/8th research, 2/8 clinical) at VAPHS. As part of her clinical responsibilities, she is a facilitator in the fellows' outpatient pulmonary clinic 1/2 day per week and has her own outpatient pulmonary clinic 1/2 day per week. She is also the director of the pulmonary function lab.

3.0 * **Will off-site ancillary service facilities (e.g., radiology services, central labs, non VA space, etc) be used for this study?**

( ) Yes (•) **No**

If yes, please provide the location and a brief description of the project activities to be conducted at the off-site ancillary facilities:

4.0 * **Will a firm be contracted to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects' research?**

○ Yes ◉ **No**

If yes, please provide a description of the contracted service(s):

* Please specify the IRB that has oversight of the firm's activity(ies):

Name of Site / Institution	IRB Approval Document	FWA Number

There are no items to display

5.0 Collaborations

Please list any non-VAPHS institutions or individuals (i.e. co-authors, mentors, etc.) that you will collaborate with and describe their specific role in the research:
Frank Sciurba, MD will be an unpaid consultant on this study. Dr. Sciurba is a Professor of Medicine in the Division of Pulmonary, Allergy and Critical Care Medicine at the University of Pittsburgh. Dr. Sciurba has been the Director of the pulmonary rehabilitation program at the University of Pittsburgh since its inception in 1996. He is an internationally recognized expert in pulmonary rehabilitation and exercise physiology and recently received NIH funding as a co-investigator on a project examining the impact of pulmonary telerehabilitation on clinical outcomes post-lung transplantation. Dr. Sciurba is also Dr. Field's mentor. He will provide guidance in the design and modification of the exercise prescriptions during this study. He will not receive any identifiable information (name, date of birth, social security number, addresses) pertaining to study participants and no study data will be transferred to him or the University of Pittsburgh. Guidance on exercise prescriptions will be provided through regularly scheduled discussions with the PI, Dr. Field.

5.1 If this is not Multi-Site Research, please upload the appropriate written agreement(s) here:

Name

There are no items to display

ID: Pro00002952 View: 1.5 Project Information

1.0 Does the project involve any of the following (check all that apply):

	Type
☐	Biological Hazards (including human biological specimens)
☐	Chemicals
☐	Ionizing radiation or use of radioactive materials
☐	Drug, Biological, or Nutritional (e.g. herbal or dietary) Supplement

2.0 Project Focus (check if applicable):

	Type
☐	Traumatic Brain Injury (TBI)
☐	Post Traumatic/Post Deployment Stress Disorder (PTSD/PDSD)

☐ Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

3.0

KEYWORDS

Please provide a minimum of 3, maximum of 6 keywords. Please use MeSH terms.

* pulmonary disease, chronic obstructive

* rehabilitation

* muscular atrophy

4.0 * **Please describe the type of study:**
This is a single-center, randomized, unblinded pilot study of an eight-week home-based pulmonary telerehabilitation program versus usual care in male and female veterans with COPD initiated immediately following hospitalization with an AECOPD. Outcome measures will include change in physical activity levels, maximal handgrip and quadriceps muscle strength, functional exercise performance, and health-related quality of life scores following the pulmonary telerehabilitation intervention versus usual care.

5.0 * **Will any of the research being conducted as a part of this study be used to fulfill academic requirements (e.g., master's thesis, dissertation, or other academic program requirements necessary to obtain a degree/certification, etc.)?** ○ Yes ◉ **No**

ID: Pro00002952 View: 1.6 (CR) Study Locations

Study Locations

1.0 * **Please add the local sites where this study will be conducted:**

	Location
View	VAPHS University Drive Division

If Other, Please Specify:

ID: Pro00002952 View: 1.6.1 (CR) Multi-Site Study

1.6.1 Multi-Site Study

1.0 * **Is this a multi-site study:**

○ Yes ◉ **No**

ID: Pro00002952 View: 1.7 Section Chief and Service Line VP approvals

Please upload the approval of the Section Chief, if applicable and the Service Line VP.

1.0 * **Institutional Approval Document:**
Field Conduct of Research PJS.pdf(0.02)

ID: Pro00002952 View: 2 Study Objectives & Design

Study Summary

1.0 **Funding End Date:**
3/31/2021

2.0

*** Abstract. Please provide a brief description of the study**.

Pulmonary telerehabilitation programs have been shown to have a high acceptance and adherence rate and lead to improvement in exercise capacity and quality of life in stable COPD. However, data regarding the feasibility and impact of pulmonary telerehabilitation following hospitalization for an AECOPD on physical activity levels, muscle function, exercise capacity, and health-related quality of life are lacking. Our primary hypothesis is that a home-based pulmonary telerehabilitation program initiated at hospital discharge following an AECOPD is feasible in the veteran population and will result in increased physical activity and greater improvement in muscle function, exercise capacity, and health-related quality of life compared to usual care. We will test this hypothesis with the following specific aims: (1) To determine the feasibility of an eight-week home-based pulmonary telerehabilitation program in veterans with moderate to severe COPD initiated in the immediate post-hospitalization period following an AECOPD. (2) To determine physical activity levels and the magnitude and variability in changes of measurements of muscle strength, functional exercise performance, and health-related quality of life following an eight-week home-based pulmonary telerehabilitation program versus usual care initiated in veterans with moderate to severe COPD immediately following hospitalization for an AECOPD. We will randomize (1:1 allocation) 30 male and female veterans hospitalized with an AECOPD to either an eight-week, three sessions per week, home-based pulmonary telerehabilitation program that includes lower extremity endurance exercises with a cycle ergometer and upper and lower extremity strength training with 1:1 supervision via video conferencing with an exercise physiologist as well as an optional once -monthly support group via teleconferencing versus usual care. Changes from baseline in physical activity levels, handgrip and quadriceps muscle strength, exercise endurance, and health-related quality of life will be assessed following the pulmonary telerehabilitation program versus usual care. Findings from this project will contribute to the growing field of pulmonary telerehabilitation and will provide critical preliminary data for the design and implementation of a larger, randomized control trial assessing the impact of pulmonary telerehabilitation on long-term clinical outcomes following AECOPD.

3.0 *** Describe the study objectives. Please include primary aim and hypothesis, if applicable any secondary aims and hypotheses.**

A pulmonary telerehabilitation program provides a home-based option for patients unable or unwilling to participate in a traditional, center-based program. Studies have demonstrated that home-based pulmonary telerehabilitation programs are feasible, positively impact exercise endurance and quality of life measures, and are widely-accepted by patients *when initiated during periods of lung disease stability*. However, little is known regarding the feasibility or impact on physical activity, muscle function, exercise performance, and quality of life measures of a home-based pulmonary telerehabilitation program initiated immediately following an AECOPD. Consequently, we propose a two-year pilot study to evaluate the feasibility and impact of a home-based pulmonary telerehabilitation program on physical activity levels, muscle strength,

exercise performance, and quality of life measures in veterans with COPD following hospitalization with an AECOPD. Our aims include:

SA 1: To determine the feasibility of an eight-week home-based pulmonary telerehabilitation program in veterans with moderate to severe COPD initiated in the immediate post-hospitalization period following an AECOPD. *Hypothesis: An eight-week home-based pulmonary telerehabilitation program will have a high acceptance and adherence rate among veterans with moderate to severe COPD following hospitalization for an AECOPD.* We will track adherence to a home-based pulmonary telerehabilitation program consisting of eight weeks, three sessions per week of 1:1 supervised lower extremity endurance exercise and upper and lower extremity strength training, as well as an optional once-monthly support group via teleconferencing, immediately following hospitalization for an AECOPD. Exercise sessions will be conducted by an exercise physiologist via video conferencing. The support group will be conducted by the exercise physiologist or another staff member via teleconferencing. A satisfaction survey will be administered at the completion of the intervention. We will also assess factors (i.e. psychiatric attributes, social support) associated with adherence to obtain preliminary insights to optimize recruitment for a larger, randomized controlled trial.

SA 2: To determine physical activity levels and the magnitude and variability in changes of measurements of muscle strength, functional exercise performance, and health-related quality of life following an eight-week home-based pulmonary telerehabilitation program versus usual care initiated in veterans with moderate to severe COPD immediately following hospitalization for an AECOPD.

Hypothesis: Participants randomized to an eight-week, three times per week pulmonary telerehabilitation program will demonstrate increased physical activity levels and greater improvement in maximal handgrip and quadriceps muscle strength, six minute walk, one-minute sit-to-stand testing, and health-related quality of life scores at completion of the intervention compared to participants randomized to usual care. We will compare changes from baseline in physical activity levels measured by pedometer, maximal handgrip and quadriceps muscle strength, six minute walk, one-minute sit-to-stand repetitions, and St. George's Respiratory Questionnaire and Short-Form 36-item questionnaire scores in veterans with moderate to severe COPD following an eight-week pulmonary telerehabilitation program versus usual care initiated after hospitalization for an AECOPD. The effect size and variance of these measurements will be used for the statistical planning (i.e. sample size and power calculations) of a larger, randomized controlled trial.

4.0 * Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous studies that provides a basis to show that the proposed research can be carried out without undue risk to human subjects.

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States and is highly prevalent in the aging veteran population. Health care costs in COPD are largely attributable to

acute exacerbations of COPD (AECOPD), defined as an increase in shortness of breath, cough, and/or sputum production that is beyond typical day-to-day variability and usually requires a change in medication. In addition to loss of lung function, decreased quality of life, and increased mortality, AECOPD are associated with reduced physical activity, muscle dysfunction, and poorer health-related quality of life. Muscle loss and dysfunction have, in turn, been associated with increased mortality in patients with COPD. Outpatient pulmonary rehabilitation initiated in the immediate post-exacerbation period has been shown to have a positive impact on muscle

function, exercise endurance, and health-related quality of life. As such, consensus guidelines recommend the participation in a pulmonary rehabilitation program within three to four weeks of an acute exacerbation of COPD. However, efforts to initiate outpatient pulmonary rehabilitation in the post-exacerbation period are often hindered by lack of physician referral, limited patient access to pulmonary rehabilitation facilities, or low patient motivation. A home-based pulmonary telerehabilitation program initiated at hospital discharge may circumvent these barriers. Pulmonary telerehabilitation programs have been shown to be safe, have a high acceptance and adherence rate, and lead to improvement in exercise capacity and quality of life in stable COPD. However, data regarding the feasibility and impact of pulmonary telerehabilitation following hospitalization for an AECOPD on physical activity levels, muscle function, exercise capacity, and health-related quality of life are lacking.

5.0 * **Describe the overall significance of the research in terms of the problem to be studied and potential findings, as well as its relevance to the care of veterans, the VAPHS, and the VHA:**

COPD is prevalent and associated with high health care utilization and costs in the veteran population. As of 2014, 52% of the veterans seeking care within the VA system were 65 years of age or older. As the veteran population continues to age, this percentage and the burden of chronic diseases such as COPD are anticipated to increase. Pulmonary rehabilitation is a key component to the management of patients with COPD but is not always a feasible option for the veterans that we care for. Only one-quarter of veterans live within 60-minutes transit time from a VA medical facility and even a lesser proportion live within one-hour distance from a VA facility offering specialized medical services such as pulmonary rehabilitation. This distance creates a tremendous burden for patients attending outpatient pulmonary rehabilitation programs, which typically require attendance two to three times per week. While some veterans may be eligible for pulmonary rehabilitation provided at a nearby non-VA facility, others living in rural areas typically do not have access to any rehabilitation program. We propose to test the feasibility of a home-based, pulmonary telerehabilitation program that will solve the issue of geographical inaccessibility and provide a service that may have meaningful impacts on exercise capacity and quality of life in our veterans with COPD.

6.0 **Please upload any additional documents:**

Name	Version
There are no items to display	

Required Reviews

1.0

Type of Submission:

New study

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

2.0 * **Requested Review Type:**

	Name
○	Exempt
○	Expedited
◉	**Full IRB Review**
○	Not Human Subject Research

3.0

	Please check which of the following Service Lines/Departments/Entities will be impacted or used in the conduct of this study	**Upload Letter of Support**
☐	Clinical Support	
☑	Medical Specialty	Haller Service Line Support Letter(0.01)
☐	Investigational Drug Service	
☐	Imaging	
☐	Community Based Care	
☐	Patient Care Services	
☐	Behavioral Health	
☐	Primary Care	
☐	Surgical Specialty	
☐	Critical Care	
☐	Clinical Trials Center	
	☐ Regulatory Coordinator Support Core	
	☐ Clinical Coordinator Support Core	

	☐ Ancillary Support Core	
	☐ Data Support Core	
☐	Research Registry Registry Number:	
☐	Other	

If Other, please specify:

ID: Pro00002952 View: 3 Research Design

Methods & Procedures

1.0

*** Does this research study involve any of the following:**

	Name
☐	Deception
☐	Interview/Focus Groups
☐	Use of Drug, biological, or nutritional (e.g., herbal or dietary) supplement (investigational or FDA approved)?
☐	Use of medical devices
☐	Prospective Analysis of Specimens
☐	Banking of Specimens-Data
☐	Retrospective use of specimens
☐	Audio/Video Recordings or Photographs
☐	Honest Broker or other similar service
☑	**None of the Above**

ID: Pro00002952 View: 4 Research study methods

Research Study Methods

Describe all study related procedures following enrollment of a subject in this study.

Please see Section 6 for where the study team defines when a subject will be considered enrolled in the study.

1.0

*** Research Procedures/Interventions:**

Study Interventions:

Pulmonary Telerehabilitation Intervention Group: The intervention will consist of an eight-week, three sessions per week, home-based pulmonary telerehabilitation program that will incorporate both lower extremity endurance exercise and upper and lower extremity resistance training. **Subjects randomized to the study intervention will also participate in a optional once monthly support group via group phone call through a reserved VANTS line. This phone conferencing consisting of an educational topic (i.e. inhaler use, understanding COPD) and group discussion.** Participants randomized to the intervention arm will receive a tablet with VA Video Connect software installed for video conferencing, a portable cycle ergometer, and a set of exercise resistance bands of varying resistance (extra-light, light, medium, heavy, extra-heavy). ***Patients will also be given an pedometer at hospital discharge to be worn everyday following discharge to track the patient's physical activity. Patients will receive a pedometer diary from study staff to record their daily steps from the pedometer.*** We also contact participants by telephone weekly to document their pedometer count. They will be permitted to keep the pedometer, cycle ergometer and resistance bands, at the completion of the study.

For safety purposes, participants in both the intervention and usual care group will also be enrolled in the hospital's telehealth program, which consists of daily monitoring of pulse oximetry, heart rate, blood pressure, and weight and regular contact with a telehealth provider. They will receive a pulse oximeter, automated blood pressure cuff, and scale as part of this program. An exercise physiologist will meet with participants randomized to the intervention group prior to hospital discharge but after informed consent is obtained to conduct a minimum of one to two face-to-face inpatient bedside pulmonary rehabilitation sessions. These sessions will be used to guide development of an individualized exercise prescription, determine participant oxygen requirements with exercise, and to assess participant safety. **Within one to six weeks post-discharge, participants in the intervention arm will begin pulmonary tele rehabilitation** sessions via 1:1 video conferencing with the exercise physiologist/study coordinator. The exercise physiologist/study coordinator will be located at VAPHS during these video conferencing sessions. These sessions will consist of: *(1)* a brief pre-exercise interview to assess symptoms and vital signs (pulse oximetry, pulse, blood pressure); *(2)* a warm-up period consisting of upper and lower extremity stretching exercises; *(3)* cycle ergometry with resistance settings and goal duration determined by the individualized exercise program developed prior to hospital discharge; *(4)* upper and lower extremity strength training with resistance bands; *(5)* a post-exercise debriefing interview to assess symptoms and post-exercise vital signs. Subjects will be offered the opportunity to enroll in a traditional facility-based pulmonary rehabilitation program.

Usual Care Group: Participants randomized to the usual care arm will also be enrolled in our institution's telehealth program, will receive an automatic blood pressure monitor, portable pulse oximeter, and scale. **Patients randomized to Usual Care will also be given an pedometer at hospital discharge to be worn everyday following discharge to track the patient's physical activity. *Patients will receive a pedometer diary from study staff to record their daily steps from the pedometer.*** We

also contact participants by telephone weekly to document their pedometer count. They will be permitted to keep the pedometer at the completion of the study.

Participants will be in regular contact with a telehealth provider. A study team member will meet with participants randomized to the usual care arm prior to discharge but after informed consent is obtained to discuss the importance of exercise and will encourage exercise (strength training, light aerobic activity such as walking or cycling) a minimum of 20-40 minutes three times per week at discharge. **The usual care group will not receive a cycle ergometer or resistance bands and will not participate in the VANTS conference call support group. Patients randomized to the control group will be offered home telerehab enrollment following completion of the study.**

Subjects in both the intervention and usual care group will receive all of the necessary information needed to participate in regular pulmonary rehabilitation. If an enrolled subject arranges to begin participation in a facility-based pulmonary rehabilitation before the conclusion of the study period, the subject will need to contact the study team to discuss withdrawal from study participation.

Development of the Initial Exercise Prescription: The exercise prescription will be developed based on exercise performance and self-reported modified Borg dyspnea scores, a scale widely used in both the clinical and research setting to measure a patient's perceived shortness of breath and effort, during the six minute walk and bedside pulmonary rehabilitation sessions. During the bedside sessions, the exercise physiologist/study coordinator will select the resistance setting on the cycle ergometer that allows the participant to perform five minutes of lower extremity cycle ergometry while achieving Borg scale ratings between four and six in accordance with the American Thoracic Society (ATS)/European Respiratory Society (ERS) Guidelines. Alternatively, interval training, which has resulted in similar improvements in walk distance and quality of life scores, will be used for those participants unable to perform five minutes of cycle ergometry. During the resistance training exercises, the resistance band workload that causes fatigue after eight to twelve repetitions will be selected for each target muscle group. Exercise performance during these bedside sessions combined with heart rate and exercise performance during six minute walk will be used to develop an individualized exercise prescription for home pulmonary telerehabilitation. Dr. Sciurba will provide guidance as needed on developing the initial exercise prescription for each participant.

Modification of the Exercise Prescription: The exercise prescription will be adjusted during the eight-week intervention to achieve modified Borg dyspnea scores of four to six during cycle ergometry and to target one to three sets of eight to twelve repetitions of each resistance training exercise per established guidelines. The resistance band level will be increased when a participant is able to complete three sets of twelve repetitions using correct technique through the full range of motion. Dr. Sciurba will provide guidance as needed on modification of the individualized exercise prescriptions throughout the eight-week intervention for each participant based on their performance. Other factors, including heart rate and blood pressure during exercise, will be considered when modifying the exercise prescriptions.

Measurement of physical activity: *Participant activity will be measured with an pedometer provided at* hospital discharge. *The pedometer* will be worn every day to track the participant's physical activity.

Safety and Oxygen Monitoring: Oxygen saturations will be continuously monitored during the six minute walk testing and inpatient bedside pulmonary rehabilitation sessions. Any participant demonstrating oxygen desaturations during these activities will undergo a formal exercise desaturation study to determine oxygen requirements prior to hospital discharge. In addition, vital signs will be monitored before, during, and after each beside pulmonary rehabilitation session. These sessions will allow investigators to assess participant safety with exercise and to disqualify any participants that are unable to participate safely in endurance and/or resistance training. Finally, participants will be provided an automated blood pressure cuff and pulse oximeter to allow for intermittent monitoring of blood pressure and continuous monitoring of oxygen saturation and heart rate during the home pulmonary telerehabilitation sessions. Prior studies have shown home-based pulmonary telerehabilitation programs to be safe, even in severe COPD. However, if the exercise physiologist has any concern with participant safety during the home-based telerehabilitation sessions, emergency services will be immediately contacted.

Handgrip and quadriceps muscle strength testing: Handgrip strength of the dominant hand will be measured with a hand dynamometer. Three measurements will be taken with a 60 second recovery period between trials. The average maximal force across trials will be calculated as the final handgrip strength. Quadriceps muscle maximal force (kilogram-force, kgf) will be measured with a Keiser leg press, equipment available in Dr. Forman's research center, **in those participants willing to return within approximately one week post-discharge for muscle strength measurements. This test will be optional.** One repetition maximum (1RM) measures will be obtained by progressively increasing resistance until the participant is unable to successfully complete one repetition. Peak muscle power will be measured at 40, 50, 60, 70, 80, and 90 percent of the 1RM 30 minutes after the 1RM measurement was obtained.

Six Minute Walk testing:

A six minute walk test will be performed by a study member. Data from the six minute walk test (distance walked, blood pressure and heart rate pre/post-procedure, symptoms pre, post-procedure) will be recorded on a de-identified study form, kept in the participant's de-identified study chart, and entered into the study data base.The six minute walk test is a validated, simple test that is responsive to changes in exercise endurance following pulmonary rehabilitation in COPD patients both during stable disease and following acute exacerbations. Exercise capacity will be defined by the six minute walk test. The six minute walk will be repeated following eight weeks of either the pulmonary telerehabilitation intervention or usual care. Participants' perception of dyspnea and exertion will be assessed at the end of the six minute walk testing with the ten point Borg dyspnea and leg fatigue scale, which ask about the degree of shortness of breath and leg fatigue. The six-minute walk test is an easy to perform and practical test that measures the distance that a patient can walk on a flat, hard surface in a period of six minutes.

Sit-to-stand testing: The one-minute sit-to-stand test has been shown to be reliable, valid, and responsive to change in exercise capacity following pulmonary rehabilitation in individuals with COPD. The test consists of the participant standing at full leg extension from a sitting position at their own pace as

often as possible during a one minute testing interval. The participant is permitted to stop at any time during the one minute interval if necessary. An armless chair is used for testing and the participant is asked to fold their arms across their chest during testing. **One test will be performed prior to discharge and another sit to stand will be performed following eight weeks of either the pulmonary telerehabilitation intervention or usual care.** The participants' perception of dyspnea and exertion will be assessed following each test with the ten point Borg dyspnea and leg fatigue scale.

Health-related quality of life assessments: Health-related quality of life will be assessed with the St. George's Respiratory Questionnaire (SGRQ) and the Short-Form 36-Item Questionnaire (SF-36) prior to hospital discharge and following eight weeks of either the pulmonary telerehabilitation intervention or usual care. The SGRQ is a disease-specific questionnaire validated to measure health status in patients with COPD. Total SGRQ scores range from 0-100 with higher scores indicating greater symptoms burden. The minimal clinically important difference is a difference of four points in the total SGRQ score. The SF-36 consists of 36 questions spanning nine health domains and is a valid measure of health-related quality of life in COPD that is responsive to change following a pulmonary rehabilitation intervention.

Participant satisfaction survey: Participants will be administered a survey by the study coordinator after completion of the eight-week pulmonary telerehabilitation intervention that will require them to respond to statements related to their satisfaction with the home-based program using a five point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). Statements will address ease of use of the video conferencing modality, acceptability of exercise components, perceptions of impact on muscle strength and exercise endurance, and willingness to participate in additional pulmonary telerehabilitation. Questions regarding social support, psychiatric attributes, and other factors potentially associated with program adherence will also be asked in order to gain preliminary insights to optimize recruitment for a larger, randomized controlled trial of pulmonary telerehabilitation.

Please upload a table of procedures if applicable.
The study procedures table must be completed for:
- All Greater than Minimal Risk (GTM) studies; and
- All Minimal Risk studies that use Standard of Care or Usual Care/Interventions.

Name	Modified Date
Table of procedures	3/2/2021 12:56 PM

2.0

* **Will Usual Care Procedures/Interventions be used?"**

(•) **Yes** ( ) No

If yes, please specify and include a description of what the usual care or expected level of care is at VAPHS (e.g., medications, testing, timing, etc.) for patients, similar to those individuals that meet the inclusion/exclusion criteria for this research study:
Those participants who demonstrate oxygen desaturations during the bedside pulmonary telerehabilitation sessions or during any of the baseline study procedures will be referred for a formal home oxygen evaluation, which would be considered a usual care procedure for any patient demonstrating low oxygen levels.

Pulmonary rehabilitation is likewise considered standard of care for patients with COPD. This is traditionally performed in a facility-based setting, although a growing interest in pulmonary telerehabilitation has developed over the past several years, particularly given the inaccessibility of facility-based programs to a large number of patients. VAPHS currently does not have a facility-based pulmonary rehabilitation program. We are working toward developing a pulmonary telerehabilitation program that we can offer our COPD patients but resources will be limited. Most COPD patients do not enroll in facility-based pulmonary rehabilitation programs in the weeks following hospitalization for an acute exacerbation of COPD.

2.1 If Usual Care Procedures/Interventions will be used, who is the individual or entity responsible for relevant aspects of the usual care (i.e., which of the above usual care activities will the research study team be responsible for)?:
The study team will be responsible for placing the inpatient consult for the home oxygen evaluation prior to discharge. The study team will be fully responsible for the inpatient pulmonary rehabilitation and pulmonary telerehabilitation sessions.

2.2 Does the usual care at VAPHS for the condition of interest in this research study differ from national guidelines/recommendations (i.e. standard of care)?

○ Yes ◉ **No**

If yes, please describe the differences:

2.3 Are any procedures that are considered standard for this patient population performed more frequently than usual care?

○ Yes ◉ **No**

If yes, please indicate which time points are considered usual care and which are considered research.

2.4 If there is more than one standard, does VAPHS limit which one is followed (e.g. warfarin use for atrial fibrillation vs. one of the newer anticoagulants).

○ Yes ◉ **No**

If yes, please explain:

3.0

* **Does clinical expertise need to be enlisted?**

○ Yes ◉ **No**

If yes, please provide the provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties, if the investigator is not a clinician [i.e. reviewing the data, adverse events, and new study findings; also making required decisions to protect the health of the subject (e.g., stopping the participant's involvement in the study or determining when to notify the subject or the subject's health care provider of information that may affect the health of the subject)]:

4.0 **Please upload any surveys, questionnaires, and data collection forms.**

	Document	Description	Version Number
View	Six Minute Walk(0.01)		0.01
View	60 SECOND SIT TO STAND(0.01)		0.01
View	Baseline Visit Checklist(0.02)		0.02
View	BORG SCALES(0.01)		0.01
View	Follow up Visit Checklist(0.02)		0.02
View	Home Based Pulmonary Rehab(0.01)		0.01
View	Muscle Strength Form Hand Grip Strength/ Leg Press (0.01)		0.01

View	Participant Information Form_telerehab.docx(0.02)	0.02
View	Participant Screening Sheet. Inclusion _ Exclusion(0.03)	0.03
View	Pedometer Diary Patient(0.01)	0.01
View	Pedometer Weekly Documentation (0.01)	0.01
View	Pulmonary Telerehabilitation Participation Survey.docx(0.02)	0.02
View	sf36.pdf/ Medical Outcomes(0.02)	0.02
View	SGRQ(0.04)	0.04
View	sit to Stand(0.01)	0.01
View	Vitals Form(0.01)	0.01

ID: Pro00002952 View: 4.1 Research study methods: analysis Plan

1.0 * **Please describe the analysis plan for the study** *(it is acceptable to refer to the sponsor/multi-site protocol for section if applicable):*

The distributional characteristics of the outcome measures and change in outcome measures between study groups will be determined using appropriate descriptive statistics (e.g. mean, median, standard deviation, range) and graphical summarizations (e.g. histograms, boxplots, line plots). The purpose of this pilot study is to generate preliminary data on the expected effect size and variance of the outcome measures to facilitate planning (i.e. sample size calculations and power analyses) of a larger, randomized controlled trial. As such, we acknowledge that, given our small sample size (n=30, 15 participants per group), we likely will not have the power to detect a significant statistical or clinical difference in outcome measures between the intervention and usual care groups. However, we will perform exploratory analyses to compare changes in outcome measures between groups using a Student's t-test or nonparametric tests when appropriate.

ID: Pro00002952 View: 5 Sub-Studies

1.0 * **Is there a sub-study or are there sub-studies associated with this study?**
There is no sub-study associated with this study.

ID: Pro00002952 View: 6 Study Population Summary

Study Population Summary

1.0 * **What is the maximum number of subjects you plan to enroll at VAPHS?**
We plan to enroll 38 participants, accounting for 25% attrition, to result in 30 participants (15 intervention, 15 control) completing baseline and eight-week follow up testing.

2.0

* **Do you plan on enrolling patients into different categories:**

(●) **Yes** ( ) No

If yes, please explain:
We will randomize 30 eligible participants hospitalized with an acute exacerbation of COPD in a 1:1 allocation to either the eight-week home-based pulmonary telerehabilitation program intervention versus usual care prior to hospital discharge.

3.0 **If this is a multi-site study, indicate the projected total subject accrual:**
N/A

4.0

*** Please provide a justification for the sample size:**

To meet our recruitment goal of 30 subjects over a one-year time interval, we will be required to enroll an average of 2-3 participants per month. A review of our COPD admission data shows that the medicine service at the VAPHS admits a mean of 28.4 (SD 8.7, range 15-43) patients per month with a primary diagnosis of COPD with acute exacerbation. Therefore, we anticipate no difficulty with recruitment for this study. We have not performed a sample size calculation given that this is a pilot study to generate preliminary data for the planning of a larger randomized controlled trial (including data to calculate estimated sample size).

ID: Pro00002952 View: 6.1 Study Population

Study Population

1.0 *** Check all that apply to describe your study population:**

	Study Population
☐	Non-Veterans
☐	Special Populations
☑	**Veterans**
☐	Vulnerable populations
☐	Other

2.0 *** Indicate the inclusion criteria for enrollment:**

(1) Male and female veterans age 40-80; (2) Moderate or severe COPD with a forced expiratory volume in 1 second - forced vital capacity ratio (FEV1/FVC) < 0.70 and FEV1 < 80% predicted; (3) Hospitalization with a primary diagnosis of AECOPD, defined as an increase in shortness of breath, cough, and/or sputum production beyond the normal day-to-day variation necessitating a change in regular medication when other causes of increased shortness of breath, cough, and/or sputum production have been ruled out; (4) Capable of operating a tablet independently with adequate vision and hearing. The inclusion criteria should select for COPD patients with significant pulmonary disease that fall within an age range where age-related changes in muscle function are not the dominating factor.

3.0 *** Indicate exclusion criteria for enrollment:**

(1) Acute hypercapneic respiratory failure with a requirement for invasive mechanical ventilation during hospitalization; (2) A diagnosis of myocardial infarction during hospitalization or unstable cardiac or neurologic disease at discharge; (3) Currently enrolled in a pulmonary rehabilitation program or completion of a pulmonary rehabilitation program within the past 6 months; (4) A medical condition that makes exercise unsafe (includes upper and lower limb strength training and lower limb cycle ergometry). This will be determined by the following- screen for these through chart review, discussion with the patient (do they have any known cardiac issues, do they have chest pain with exertion, are they lightheaded with exertion), discussion with the physicians caring for the patient in the hospital, and direct observation and assessment during the bedside pulmonary rehab sessions (that were built into this study for safety purposes). (5) Inclusion in another greater than minimal risk study. Exclusion criteria were selected to minimize bias and to maximize patient safety when participating in a home-based exercise program.

4.0 **If there are any age, ethnic, language, or gender-based exclusion criteria, including the exclusion of any pregnant or lactating women, or those of child-bearing potential, please provide justification:**

The age range of 40-80 was selected in order to select for COPD patients with significant pulmonary disease that fall within an age range where age-related changes in muscle function are not the dominating factor.

5.0 Please specify why vulnerable subjects and/or special populations will not be enrolled:

6.0 With some exceptions as listed in VHA Handbook 1200.05, incompetent subjects cannot be enrolled in VAPHS approved research. Specify that you will not enroll incompetent subjects and the general rules to be used in making that determination:
We will not enroll incompetent subjects.

ID: Pro00002952 View: 7 Risk/Benefit Assessment-Risks

Risk/Benefit Assessment-Risks

1.0 * Risk classification for this study (select one).

	Name
○	Minimal Risk
◉	**Greater than Minimal Risk**

2.0 * Basis for making the above recommendation:
The participants will be undergoing an exercise intervention as well as muscle strength testing and six minute walk testing, all of which are greater than minimal risk procedures.

3.0 * Describe the safety precautions that will be taken to minimize risks/harms:
Oxygen saturations will be continuously monitored during the six minute walk testing and inpatient bedside pulmonary rehabilitation sessions. Any participant demonstrating oxygen desaturations during these activities will undergo a formal exercise desaturation study to determine oxygen requirements prior to hospital discharge. In addition, vital signs will be monitored before, during, and after each beside pulmonary rehabilitation session. These sessions will allow investigators to assess participant safety with exercise and to disqualify any participants that are unable to participate safely in endurance and/or resistance training. Finally, participants will be provided an automated blood pressure cuff and pulse oximeter to allow for intermittent monitoring of blood pressure and continuous monitoring of oxygen saturation and heart rate during the home pulmonary telerehabilitation sessions. Prior studies have shown home-based pulmonary telerehabilitation programs to be safe, even in severe COPD. However, if the exercise physiologist has any concern with participant safety during the home-based telerehabilitation sessions, emergency services will be immediately contacted.

4.0 * Provide details regarding the nature of each risk using the area provided below:

	Risk Name
View	Questionnaires
View	Pedometer
View	Measurement of handgrip and quadriceps strength
View	Sit-to-stand testing
View	Participating in the pulmonary telerehabilitation program
View	Six Minute walk

5.0 * Do you plan on using the research answering service: ◉ **Yes** ○ No

If yes, please Upload the research answering service form:
Research_Answering_Service - SPiRE.doc(0.01)

6.0 If your study involves a treatment or intervention, please upload the Patient ID Card:

ID: Pro00002952 View: 7.1 Risk/Benefit Analysis-Potential Benefits and Alternatives

Risk/Benefit Analysis-Potential Benefits and Alternatives

Describe any potential for benefits to participants in this study:

1.0 * **Direct and Indirect Benefits to Subjects:**
Pulmonary rehabilitation is known to improve outcomes in COPD, both in stable disease and following acute exacerbations. Many patients are unable to attend pulmonary rehabilitation at a rehabilitation facility due to geographical inaccessibility, transportation issues, etc. This study will provide an alternative to traditional facility-based pulmonary rehabilitation to a group of patients at highest risk for poor outcomes and may have a positive impact on exercise tolerance, physical activity levels, and quality of life in this patient group. This study should lead to a larger, randomized controlled trial to study this intervention in a larger group of patients.

2.0 * **Describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study:**
Subjects who choose not to participate may choose to exercise on their own or to participate in a different pulmonary rehabilitation program.

ID: Pro00002952 View: 8 Methods of Recruitment and Retention

Recruitment Methods and Materials used for Retention

1.0 * **Select recruitment methods used on this study:**

	Name
☐	Mail Campaign
☐	Referral by independent source
☐	Advertising such as fliers, letters, or ads (newspaper, TV, radio)
☐	Web Site
☐	Research registry
☐	Selected from pre-existing records
☐	Pre-existing relationship with participants
☑	**Other**

If Other Methods Specify:
We will receive a list of all admissions to the inpatient wards (non-critical care units) with a primary diagnosis of acute exacerbation of COPD and may also review the patient floor census lists for eligible patients. We will also ask the medicine teams on the floor to contact us if they have a patient that they think meets eligibility criteria and is interested in the study and will review the inpatient census with the charge nurses on the floors to identify anyone admitted with an acute exacerbation of COPD. We may also recruit from patients referred to the inpatient pulmonary consult service for an acute exacerbation of COPD. For all recruitment methods, the health care provider will ask the patient first if they are interested in the study and willing to talk to someone from the study team prior to any study member approaching the potential participant.

2.0 * **Specify how subjects will be identified and how study eligibility will be determined:**
We will follow the following procedures to identify subjects and determine eligibility: (1) We will review the inpatient admission and census lists each day for all patients admitted to the inpatient wards (non-critical care units) with a primary diagnosis of COPD. The medicine teams will also be asked to contact the study team if they have a patient that meets eligibility criteria and is interested in the study. We will also review inpatient censuses with the charge nurses to identify potential subjects. We will also be alerted by the pulmonary fellow or pulmonary attending if a patient with an acute exacerbation of COPD is referred to the pulmonary inpatient consult service (2) We will review the charts for inclusion and exclusion criteria (HIPAA authorization waiver requested) (3) When subject eligibility is determined, the health care team caring for the patient will be notified and asked to approach the patient, introduce the study, and ask if someone from the study team can come and discuss the study with them (4) For interested patients, we will meet with them at bedside in the hospital and review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subjects will undergo the written informed consent process.

3.0

*** Provide the location (or locations) of the sites where participants will be recruited:**

inpatient medical wards at VAPHS.

4.0 **Please include information regarding any advertisements (print, TV, radio, etc) that will be used to recruit subjects including a general description of where this information will be posted:**
We will post a flyer in the nursing stations that describes the study for the nursing and medical staff's reference. The study coordinators' phone numbers will be listed on this flyer so that the nursing/medical staff can contact someone if they have a patient that they think is eligible for the study.

5.0

Please UPLOAD the documents that will be used for recruitment and an introductory statement or letter to accompany consent for those studies obtaining written informed consent using methods such as fax, email or mail (if applicable). Please also upload any screening/recruitment questions that will be verbally asked of potential research subjects. Also, if you will be providing any retention materials, please upload them here.

Name	Reviewer	Modified Date	Version Number
Spire Poster	Calgaro, Linda Lee	1/22/2020 11:37 AM	0.01

ID: Pro00002952 View: 9 Informed Consent

Informed Consent

1.0

*** Indicate the types of consent that will be involved in this study (check any or all that apply):**

Informed Consent Category
Written/signed consent by subject

2.0 *** Waivers: If you are applying for any waivers of consent (check any or all that apply):**

	Name
☐	Waiver of Informed Consent
☑	**Waiver of HIPAA Authorization**
☐	Waiver of Documentation of Informed Consent (telephone consent, verbal script)
☐	No Waiver at all

3.0 *** Will this study include non-English speaking participants?**

○ Yes ◉ **No**

ID: Pro00002952 View: 9.1 Waiver of HIPAA

You have indicated you are requesting a waiver of HIPAA.

1.0 *** Is the request only for Screening/Recruitment purposes?**

◉ **Yes** ○ No

If yes, please describe your screening/recruitment method:

We will follow the following procedures to identify subjects and determine eligibility: (1) We will review the

inpatient admission and census lists each day for all patients admitted to the inpatient wards (not critical care units) with a primary diagnosis of COPD. The medicine teams will also be asked to contact the study team if they have a patient that meets eligibility criteria and is interested in the study. We will also review the inpatient medicine census with the charge nurses. We will also have patients referred from the inpatient pulmonary consult service. (2) We will review the charts for inclusion and exclusion criteria (HIPAA authorization waiver requested) (3) When subject eligibility is determined, the health care team caring for the patient will be notified and asked to approach the patient, introduce the study, and ask if someone from the study team can come and discuss the study with them (4) For interested patients, we will meet with them at bedside in the hospital and review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subjects will undergo the informed consent process.

If no, the request is for the full study (e.g. retrospective chart reviews and certain observational studies)

Please describe the types of records and/or databases to be accessed:

CPRS electronic medical record will be accessed for screening purposes.

THE IDENTIFIABLE INFORMATION BEING REQUESTED:

Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must select Names, Addresses and Social Security Numbers as that information will be disclosed for payment purposes.

2.0 * **Identifiable Information per HIPAA Definition**

	Name
☐	None
☐	Account numbers
☐	Biometric identifiers, including finger and voice prints
☐	Certificate/license numbers
☐	Device identifiers and serial numbers
☑	**Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)**
☐	Email Address
☐	Fax Numbers
☐	Full-face photographic images or any comparable images
☑	**Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)**
☐	Health plan beneficiary numbers
☐	Internet Protocol (IP) address numbers
☑	**Medical Record Numbers**
☑	**Name or any derivative of name such as initials**
☑	**Social Security Numbers**
☑	**Telephone Numbers**
☐	URLs (Web Universal Resource Locators)

- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)

3.0 * Patient Protected Health Information:

Name
☑ **Demographic Information (e.g., Name, Address, Phone Number, Social Security Number**
☐ Billing and Payment Information
☑ **Hospital or Medical Records**
☑ **History and Physical Exam Notes**
☐ Mental Health Records
☐ Data Previously Collected for Research Purposes
☑ **Progress Notes**
☑ **Consultation Reports**
☑ **Laboratory Test Results**
☑ **Operative Reports**
☑ **Other**

Please indicate the 'Other' Patient Protected Health Information:
imaging reports

4.0 Other Health Information:

Name
There are no items to display

ID: Pro00002952 View: 9.1.1 Waiver of HIPAA - More Information

Waiver of HIPAA- More Information

1.0 * Describe how the identifiable information is to be used and/or disclosed only by members of the research team and the following persons *(identify with specificity and justify the need to disclose the information to anyone outside the VHA.)* Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must also describe this disclosure to representatives of the VA for administrative purposes here.

Also describe how this activity meets the "minimum necessary standard" described in the HIPAA Privacy Rule:
The patients electronic medical record will be reviewed for study eligibility. A screening log will be kept on a password protected spreadsheet in the PIs shared research drive (PulmResearchJF) or within the RedCap study database, also password protected. This screening log will include the patient's last name, last four digits of his/her social security number, an indicator of eligibility, an indicator of enrollment, and any other information pertinent to the screening process. No paper records will be kept as part of the screening process.

The proposed study poses minimal risk to the privacy of the subjects because...

2.0 * Describe how the identifiable information will be protected from improper use or disclosure by (detail how this will be accomplished including the limitations of physical or electronic access to

the information and other protections):
The identifiable information will be maintained on the PIs shared drive on a password-protected spreadsheet and/or database. Only study members will have access to the spreadsheet password.

3.0 * **Describe how the identifiers will be destroyed at the earliest opportunity consistent with the research (discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them) (Note: At this time, identifiers used for research screening and all other screening records must be retained indefinitely and this must be documented by checking "Other" below):**
All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

* **When will screening data be de-identified or destroyed:**

Name
completion of study accrual

If Other, please describe:

4.0 * **Describe how the identifiable information will not be reused or disclosed to any other person or entity outside the VHA other than the manner described in the protocol, except as a required by law, for authorized oversight of this research study, or as specifically approved for used in another study by an IRB:**
The identifiable information will only be available to the study staff and will not be reused or disclosed to any other person or entity outside the VHA except as required by law or for authorized oversight of this research study.

5.0 * **Describe why the proposed study cannot be practicably conducted without a waiver of authorization: (discuss reasons why it would not be possible to obtain authorization from individual subjects. Time constraints themselves are generally not considered adequate for this justification:**
Given the fairly extensive inclusion/exclusion criteria, we would anticipate a high number of screen fails if we were to approach all veterans admitted with a COPD exacerbation for potential inclusion in the study. These potential participants are in the hospital with an acute exacerbation of their chronic illness and we would like to minimize unnecessary interruptions that would certainly occur if we did not first pre-screen COPD patient for eligibility.

6.0 * **Describe why the proposed study cannot be done without the specified identifiable information: Discuss reasons why it would not be possible to conduct the research without the identifiable information being collected.**
In order to access the patient's medical information for pre-screening, we need to access their electronic medical record that includes their name, date of birth, and social security number.

ID: Pro00002952 View: 9.4 Consent Forms & Process of Consent

Consent Forms & Process of Consent

1.0 Upload the completed forms into the correct lists below.

1.1 Informed Consent Form (clean copy):

	Document	Modified Date	Version Number
View	Consent_telerehab.doc(0.10)	3/3/2021 12:00 AM	0.10

1.2 Provider Behavior Informed Consent Form (clean copy):

Document	Modified Date	Version Number
There are no items to display		

1.3 Screening Informed Consent Form (clean copy):

Document	Modified Date	Version Number
There are no items to display		

2.0 Consent Forms (modified copy):

	Document	Modified Date	Version Number
View	Consent_ telerehab.doc tracked(0.01)	3/2/2021 11:41 AM	0.01

3.0 * Describe how, where, when, and by whom the consent process will be initiated:
The consent process will occur only after the patient's eligibility has been pre-screened (HIPAA waiver), the patient's health care provider has approached the patient and asked permission for a study member to speak with the patient, the study member (either coordinator, PI, or co-I) has confirmed the patient's eligibility in person, and the patient has agreed to participate in the study. The informed consent process will take place at the bedside of the patient and will be conducted by the coordinator, PI, or Co-I. No procedures will take place until written informed consent has occurred. Confidentiality will be assured during the bedside consent process by pulling the drape and speaking quietly to the subject during the consent process, similarly to how confidentiality is assured by the care providers when addressing medical issues in semi-private rooms.

4.0 * Will you be maintaining a Master List of Subjects?
Yes

5.0 * Describe when the subject's name will be added to the master list and how the list will be maintained in a secure fashion.
We will add a subject's name to the master list of subjects once a subject has agreed to participate in the study and the written informed consent process has taken place. This list will be maintained on a password protected spreadsheet on the PIs shared research drive.

ID: Pro00002952 View: 10.0.0 Data Security and Privacy: Data Types Storing

10.0 Data Types Collecting and Storing

1.0

Click the add button (below) to open an entry form to indicate the types and/or sources of the data that will be collected/stored as part of the project.

Instructions: **For each type/source of data that will be collected as part of the project, this includes screening data, click the add button to open an entry form that lists the types and/or sources of data. Select a source/type of the data that will be collected/stored. Then indicate what, if any, identifiers or sensitive information will be collected/stored from the source/type (None is an option). To add another source/type click "OK Add Another" button to open up a new entry form to repeat the process.**

Example 1: You are collecting data from VA Medical records including names, last 4 of SSN, and addresses. Therefore, you would select "VA medical record data" as the source, and then select in the identifiers: "Name or any derivative of name, such as initials," "Social Security Numbers," and "Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)" as the identifiers being collected.

Example 2: You are screening VA Medical Records and recording the information you use to screen (i.e.: names, last 4 of SSN, and addresses, etc.) Note: This information must be treated as a Source document, please select "Screening" as the source and then select the identifiers "Name or any derivative of name, such as initials," "Social Security Numbers,", as applicable.

*

	Data Type/Source	Collection Details	Identifiers
View	Questionnaires/Surveys, paper	Data will be collected by a study team member and will be stored on the PI's shared research drive on password-protected spreadsheets or databases.	Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89) Medical Record Numbers Telephone Numbers Social Security Numbers Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
View	VA medical record data (i.e., diagnoses, procedures, visits) via **chart review**	The data will be collected by a study team member during either the screening process or after enrollment. The data will be collected via chart review and via interview with the study participant. All collected data will be stored in the PIs shared drive in either a password-protected spreadsheet or database. Only study team members will have access to this password protected data.	Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89) Medical Record Numbers Telephone Numbers Social Security Numbers Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code) Name or any derivative of name such as initials
View	Other *Data will be collected on the Pedometer device that subjects wear.*	Results will be collected weekly by patients. Staff will call patients for the documentation of pedometer activity.	None

ID: Pro00002952 View: 10.0.1 Data Security and Privacy: Social Security Numbers

10.0.1 Data Security and Privacy: Social Security Numbers

1.0 You indicated that you will be using all or some part of the research subjects' SSNs as part of this study. Which of the following will you be using:

Real Social Security numbers	*	**Yes**	No
Scrambled Social Security numbers	*	Yes	**No**
Last 4 digits of Social Security Number	*	**Yes**	No
Other (some derivation of the SSN)	*	Yes	**No**

If other, please explain:

2.0 * Please describe how subjects' Social Security numbers will be used in this study:
We will be accessing the patient's medical records and will need to use social security numbers in their entirety or in part to access these records. We will use subjects' social security numbers in order to provide subject payment.

3.0 * Please describe the security measures that will be taken to protect SSNs.
Any data collected on subjects will be stored on the PIs shared research drive on password protected spreadsheets and databases. Only study team members will have access to this information.

ID: Pro00002952 View: 10.1.0 Data Security and Privacy: Incoming Data

10.1.0 Incoming Data

1.0 * Will data be transferred into VAPHS?
No. Data is not being transferred into this facility

ID: Pro00002952 View: 10.2.0 Data Security and Privacy: Outgoing Data

10.2.0 Outgoing Data

1.0 * Will any of the data being collected/stored be transferred outside of VAPHS?
No. The data is not being transferred outside of this facility.

ID: Pro00002952 View: 10.3.0 Data Security and Privacy: Local Data Storage Types

10.3.0 Local Data Storage Types

1.0 * How will data be stored on this project? (Select all that apply)
On Paper
Electronically

ID: Pro00002952 View: 10.3.1 Data Security and Privacy: Local Data Storage Types - Paper

10.3.1 Local Data Storage Types - Paper

1.0

*** All VA research data collected in paper must be stored in a locked room at VAPHS.**

List the room number(s) and the campus(es) where data will be stored in the text box below.

All data collected in paper will be stored in a locked filing cabinet in the Research Office Building outside the PI's coordinators' cubicle.

ID: Pro00002952 View: 10.3.2 Data Security and Privacy: Local Data Storage Types - Electronic

10.3.2 Local Data Storage Types - Electronic

1.0 * Where is the electronic data being stored? Select all that apply.
VAPHS Network (shared drive)
Other

If "Other" please describe OR if you would like to provide additional information for clarification, please elaborate in the text box below.

VA RedCAP - data entry https://vhacdwweb05.vha.med.va.gov/index.php?action=myprojects

If you selected VAPHS or VA Network (Shared Drive), please provide the name of the drive (i.e. "MySharedDriveName (\\vapthshsare) (X:)"):

file://r04pthnas21.v04.med.va.gov/PTH_Groups/PulmResearchJF/SPiRE

ID: Pro00002952 View: 10.4.0 Data Security and Privacy: Reusing Data

10.4.0 Data Security and Privacy: Reusing Data

1.0

* **Will the data collected in this study be reused in other studies?** ○ Yes ◉ **No**

If yes, please describe where the data to be reused will be stored and how access to that data will be provided and monitored:

2.0 If this research is part of a grant, please upload the Data Management Access Plan (DMAP) or Resource Sharing Plan for this study.

Name	Modified Date
09_VA_DMAP.pdf	2/14/2019 3:30 PM

ID: Pro00002952 View: 10.6.0 Data Security and Privacy: HIPAA

10.6.0 Data Security and Privacy: HIPAA

The Healthcare Insurance Portability and Accountability Act (HIPAA) prohibits the use of a person's Protected Health Information without a valid authorization.

1.0 * **Select the option which fits this study:**

	Name
○	Not applicable: No PHI is being used or disclosed by VAPHS
○	Not applicable: Waiver has been requested
◉	**HIPAA Authorization (Combined Consent and HIPAA Authorization)**
○	HIPAA Authorization (Standalone)

Upload HIPAA authorization (Standalone) here:

Document	Modified Date	Version Number
There are no items to display		

2.0 At screening will clinical personnel be asked to share potential participants PHI:

○ Yes ◉ **No**

If yes, please upload the 10-5345:

ID: Pro00002952 View: 10.7.0 Data Security and Privacy: Additional Information

10.7.0 Data Security and Privacy: Additional Information

1.0

Does this research involve...

* **...specially obtained software?** (•) **Yes** ( ) No

If yes, please describe the software and what it is being used for:

Tablets with data plans will be obtained through a VA Video Connect enrollment consult (telehealth consult). The VA video conferencing software on these tablets will be used to conduct telepulmonary rehabilitation sessions between the study participant (at home) and the exercise physiologist (at VAPHS). The tablets with data plans will be used by the study participants only for the sole purpose of participating in the telehealth video pulmonary rehabilitation sessions. No data will be stored on the tablets. Microsoft Access and Excel will not be used on the tablets. The participants will access their email on the tablets so that they can click on the video link to conduct the pulmonary telerehabilitation visit, which is how all telehealth visits are currently being conducted clinically at VAPHS and is a requirement for the software to function. The study staff will conduct visits using the VA video conferencing software on either a VA desktop computer or VA issued laptop computer. Visits will be conducted by the study staff alone in a room to guarantee subject privacy during all sessions.

We will use Office 16.0/2016 version of Microsoft Excel for data collection along with a VA RedCAP database. All information will be kept on Dr. Field's research ShareDrive (L:\PulmResearchJF), to which only study personnel have access. Both the database and Excel spreadsheets are password protected and only study personnel have access to these passwords.

No data will be downloaded from the tablets.

* **...one or more Web-based applications?** (•) **Yes** ( ) No

If yes, please describe the application and what it is being used for:

We will use the VA-approved web-based application/software that is installed on the tablets provided by the VA through the VA Video Connect enrollment consult. This application will be used to videoconference with the study participant during the pulmonary telerehabilitation sessions. The study staff will conduct visits using the VA video conferencing software on either a VA desktop computer or VA issued laptop computer. Visits will be conducted by the study staff alone in a room to guarantee subject privacy during all sessions.

VA RedCAP - data entry https://vhacdwweb05.vha.med.va.gov/index.php?action=myprojects

Participant payment will be done through the Clincard website (https://clincard.com/login/).

* **...mobile devices?** (•) **Yes** ( ) No

If yes, please describe:

VA

2.0

* **Will a Certificate of Confidentiality be obtained for this study?** ( ) Yes (•) **No**

If yes, please attach the Certificate of Confidentiality:

3.0

* **Will VA sensitive information be transported and utilized outside protected environments?** ( ) Yes (•) **No**

If you answered yes above, please upload a fully executed VAPHS Memo to Take VA Sensitive Information Outside a Protected Environment by following **these instructions** .

ID: Pro00002952 View: 10.8.0 Data Security and Privacy: Certifications

10.8.0 Certifications

1.0 * **I certify that all study staff are up-to-date and will remain up-to-date with Information Security Awareness Training, Rules of Behavior, and VHA Privacy Training.** (•) **Yes** ( ) No

2.0 * **I also certify that when an individual is no longer part of the study team, access will be removed to research study data.** (•) **Yes** ( ) No

3.0 * **I certify that all research records will be maintained in accordance with the Veterans Health Administration (VHA)Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.** (•) **Yes** ( ) No

4.0 * **I certify that any loss or compromise of any VA sensitive information (including research data), VA equipment or device, or any non-VA equipment or device that is used to transport, access, or store VA information will be reported in accordance with the reporting requirements outlined in VA Handbook 6500.** (•) **Yes** ( ) No

5.0 * **I certify that, in accordance with VA Handbook 6500, no personal laptops will be used for official VA business in conjunction with this study.** (•) **Yes** ( ) No

ID: Pro00002952 View: 11 Local Data Safety Monitoring Plan

Local Data Safety Monitoring Plan

For local studies, a data and safety monitoring plan (DSMP) must be established.

1.0 * **Please describe how the study procedures and data being collected will be continuously monitored so that changes in the risk/benefit ratio can be determined in a timely fashion during the course of the study:**

An Institutional Data and Safety Monitoring Board will be created to review this study. The initial responsibility of the IDSMB will be to approve the initiation of this clinical trial. After this approval and at quarterly intervals during the course of the trial, the IDSMB responsibilities are to:

1. Review the research protocol, informed consent documents and plans for data and safety monitoring;

2. Evaluate the progress of the trial, including assessment of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect study outcomes

3. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;

4. Review clinical center performance, make recommendations and assist in the resolution of problems reported by the PI;

5. Protect the safety of the study participants;

6. Report on the safety and progress of the trial;

7. Ensure the confidentiality of the trial data and the results of the monitoring;

8. Assist the PI by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

The IDSMB will include experts in pulmonary diseases, clinical trials methodology, and exercise physiology. Members will consist of persons affiliated with the VAPHS and/or the University of Pittsburgh, and independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to the absence of conflict of interest will be required.

2.0 * **Describe how frequently Investigators, study personnel, and the clinical coordinators involved in the study will meet and/or review study data.**

The investigators, study personnel, and clinical coordinators involved in the study will meet monthly to review study data as a group. The PI also will meet with the principal coordinator on a weekly basis.

3.0 * **Will this study use a Data Safety Monitoring Board or Data Monitoring committee?**

(•) **Yes** ( ) No

4.0 * **Will this study use a Medical Monitor?**

( ) Yes (•) **No**

Data Safety Monitoring Board/ Data Monitoring Committee

1.0 * **List the affiliations and qualifications of those monitors who are not associated with the study or describe the composition of the DSMB:**
The IDSMB will include experts in pulmonary diseases, clinical trials methodology, and exercise physiology. Members will consist of persons affiliated with the VAPHS and/or the University of Pittsburgh, and independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to the absence of conflict of interest will be required.

2.0 * **Describe how frequently the independent monitor(s) or DSMB will meet and/or review study data:**
The IDSMB will meet on a quarterly basis to review study data.

3.0 * **Describe the type of data (e.g., blinded or unblinded) to which the independent monitor(s) or DSMB will have access:**
The DSMB will have access only to blinded data.

4.0 **Document that minutes will be kept.**
Minutes of the IDSMB meetings will be kept and submitted at continuing review or more frequently if requested by the IRB.

5.0 * **Please upload the DSMB/DMC Charter:**
DSMB_charter.docx(0.01)

ID: Pro00002952 View: 12 Costs and Payments

Costs and Payments

1.0 * **Does this study have a budget?:**
(•) **Yes** ( ) No
If yes, please upload the current budget:
SPiRE_budget.pdf(0.01)

2.0
* **Will patients receive payments for this study?**
(•) **Yes** ( ) No

If yes, please upload the financial letter of support (either from the Business Service line or the Veterans Health Foundation) or documentation waiving the requirement of a letter of support:
VA Financial LOS Memo_v3_Sept2018.pdf 0.02

3.0 * **Are you paying patients using the WePay system?**
not applicable

ID: Pro00002952 View: 12.1 Costs

Costs

1.0 * **Will subjects be required to pay for any services outside of the VHA that may be required as part of participating in this research study?**
No

ID: Pro00002952 View: 12.2 Participant Payments

Participant Payments

1.0 * **Please explain how the proposed payments are reasonable and commensurate with the expected contributions of the subject:**
The participants will be paid $150 for participation in the study. They will be asked to perform baseline and 8-week six minute walk testing, muscle strength testing, sit-to-stand testing, and answer questionnaires. They will also be asked to wear a pedometer to monitor their physical activity for eight weeks. Participants

in the intervention arm will participate in a total of 24 pulmonary rehabilitation sessions. This payment is reasonable and commensurate with the number of procedures required and travel time.

2.0 * **Please provide information on how the subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. In additional the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study:**
The payments will compensate for the subject's time and travel back to the facility for follow up testing. They do not constitute undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. Subjects are free to quit the study at any time and will still be able to keep their cycle ergometer and exercise bands if randomized to the intervention arm.

3.0 * **Specify the amount, form of payment and the specific disbursement schedule of payments:**
The subjects will be paid $50 after completion of testing prior to hospital discharge (six minute walk tests, muscle strength testing, sit-to-stand testing, and questionnaires) and an additional $100 after completion of the follow-up visit, which will include the same testing procedures but only one shuttle walk test. EFT/Direct Express Debit MasterCard will be used for subject payment.

4.0 * **Are the subjects being paid employees?**
no
If yes, please describe how it will be in accordance with the SOP:

ID: Pro00002952 View: 14 References

References:

1.0

* **Please provide a list of references** *(Multi-site protocols: You may reference the page numbers in the original protocol):*

1. Sharafkhaneh A, Petersen NJ, Yu H-J, et al. Burden of COPD in a government health care system: a retrospective observational study using data from the US Veterans Affairs population. International Journal of Chronic Obstructive Pulmonary Disease 2010;5:125–32.

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ID: Pro00002952 View: 15 Miscellaneous Documents

Miscellaneous Documents

If you have any documents that need to be included in this submission, but do not fit in any of the previous sections please upload them here.

	Document	Description	Version Number
View	COVID Risk Assessment(0.01)		0.01

ID: Pro00002952 View: SF - Final Page

Final Page

You have completed your application!

Please hit "Finish" to save and exit the application. Doing so will NOT submit the application for review.

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must press the "SUBMIT STUDY" button in My Activities for this Study ID:Pro00002952.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB with any questions or concerns.

ID: Pro00002952 View: Create/Edit

Study Funding Source

1.0 * **Funding Source Name:**
Rehabilitation R&D (Prog 822)
If you can't find the Funding Source above, choose "Other" and enter it here:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Questionnaires

Common Risks:
None

Infrequent Risks:
Completing the questionnaires may make participants tired. It is possible that some of the questions may make participants feel embarrassed.

Other Risks:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Pedometer

Common Risks:
slight inconvenience

Infrequent Risks:

Other Risks:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Measurement of handgrip and quadriceps strength

Common Risks:
Shortness of breath can be expected to occur (in more than 25% of people) during and for a few minutes after testing.

Infrequent Risks:
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.

Other Risks:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Sit-to-stand testing

Common Risks:
Shortness of breath can be expected to occur (in more than 25% of people) during and for a few minutes after testing.

Infrequent Risks:
These tests are considered to carry a low risk of harm, but may occasionally cause slight soreness in muscles due to the effort involved.

Other Risks:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Participating in the pulmonary telerehabilitation program

Common Risks:
Muscle soreness and/or breathlessness may be experienced when participating in exercise.

Infrequent Risks:
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 participants will be screened prior to participation to lower the overall risk of a medical event.

Other Risks:

ID: Pro00002952 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Six Minute walk

Common Risks:
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.

Infrequent Risks:
This test is considered to carry a low risk of harm, but may occasionally cause slight soreness in muscles

Other Risks: