Official Study Title: Chronic Lung Disease and COVID-19: Understanding Severity, Recovery, and Rehabilitation Needs (LAUREL Study)

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Chronic Lung Disease and COVID-19: Understanding Severity, Recovery, and Rehabilitation Needs
(LAUREL Study)

Researchers **Study Contact Number**

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Researchers' Statement

We are inviting you to participate in a research study. The purpose of this Information Statement is to give you information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study.

PURPOSE OF THE STUDY

The purpose of this research study is to understand factors associated with COVID-19 severity, complications, outcomes, and recovery with the ultimate goal to understand the rehabilitation and care needs of Veterans post-COVID-19 infections, especially among Veterans with a chronic lung disease. We are interested in speaking with Veterans diagnosed with COVID-19, including Veterans who had very mild to severe COVID-19.

We have been approved to enroll 350 to 440 Veterans and up to 36 caregivers, family members, or legally authorized representatives of Veterans. If you are interested and eligible to participate, your participation will take about 3 to 4 hours over 12 months. Most study procedures will take place over the phone. We may also determine your health outcomes from VA electronic health record data for up to 4 years after you have joined the study to understand Veterans' long-term healthcare utilization and recovery needs post COVID-19.

STUDY PROCEDURES

Structured Phone Surveys

We will ask all Veterans who enroll in the study to answer some survey questions, which will take about 60 minutes per survey to complete. We will be asking you the survey questions over the phone at three different time points-baseline, 6 months, and 12 months. For Veterans who are interested in participating in surveys, but are unable to complete them by phone, we may offer them other options, such as asking them to complete the surveys by themselves and mail the completed questionnaires back to us. The survey can also be completed online as well. The questions will be related to demographics, your health and mental well-being, memory, and your COVID experience. Examples of the kinds of questions that you will be asked are:

- *In the past 30 days, how much difficulty did you have in standing for long periods, such as 30 minutes?*
- *Please choose one answer that best describes your mobility before COVID:*
    - *I have no problems in walking about;*
    - *I have slight problems in walking about;*

  - *I have moderate problems in walking about;*
  - *I have severe problems in walking about; or*
  - *I am unable to walk about.*
- *Were you hospitalized for COVID?*
- *I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember.*

When staff from either VA Puget Sound for VA Ann Arbor call you to conduct the surveys, we will enter most of your responses into federally-approved software called VA Research Electronic Data Capture (or VA REDCap) or Qualtrics via a secure web browser from within the VA network.

With this Information Statement, you will find the survey questionnaires and a pre-paid postcard. You do not need to review or complete the questionnaires ahead of time. We mail them to you in advance, so that when we call you to conduct the survey, you can follow along. Your feedback is important to us. By receiving feedback from Veterans who experienced COVID-19, we hope to learn what helps people in recovery and can use this information to improve rehabilitation programs in the future.

If you do not want us to call you regarding this study, check "Please do NOT contact" on the enclosed pre-paid postcard and drop it in the mail. If you are interested in participating in the study, please mark "Please contact" on the postcard and drop it in the mail. If we do not receive a response from you, a member of our study team may call you to discuss the study with you. At this time, you may ask any questions to help you decide if you want to take part in this research study.

We also are approved to send reminder text messages for upcoming study appointments (to complete a survey over the phone or through an email link). You can opt in or out of receiving text message reminders at any time in the study.

Qualitative Phone Interview

If you had a family member or friend who took care of you while you had COVID-19, we also would like to hear from them. We may ask if you would be willing to share contact information of such a person, so that we can potentially contact them for an interview. Examples of the kinds of questions that we will ask your caregivers, family members, or legally authorized representatives are:

- *What was it like for you to have someone you care for diagnosed and treated for COVID-19?*
- *Tell me about your role during their diagnosis, treatment, and recovery?*

We will audio-record the interview for documentation, data analysis, and potential use in research publications and presentations. Once the recording is transcribed, we will include the transcript as part of the data collected for the study.

Post-COVID-19 Review

We may review your post-COVID-19 recovery and health outcomes from VA electronic health record data for up to 4 years after you have joined the study to assess long-term healthcare utilization and recovery needs in Veterans who tested positive for COVID-19.

POTENTIAL RISKS AND DISCOMFORTS

Internet activity. Any activity on the internet involves risk; nevertheless, we take normal precautions to ensure our system is running the most current version of our browsing software, that we have up-to-date virus protection, and that we implement a software or hardware firewall to protect our computer and your data. By ensuring that our computer has up-to-date security measures, we reduce the risk to you and your data, but this risk cannot be completely eliminated.

Survey questions: You may be uncomfortable answering some of the questions. You can skip any question you do not wish to answer at any time.

Privacy: There is a risk of loss of privacy (confidentiality) by participating in this study. We will protect all identifying health care information with great care. We have extensive measures in place to keep this from happening and expect these measures to protect your personal information. For details on the steps we will take to protect your confidentiality, please refer to the Confidentiality section below.

POSSIBLE BENEFITS

There may be no direct benefit to you by participating in this study, although you will contribute to information that may potentially improve care for patients with COVID-19. Additionally, the information gathered may inform rehabilitation programs in the future.

OTHER INFORMATION

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits. If you decide to withdraw from the study, no new information will be collected from you; however, data already collected will continue to be part of the analyses. To withdraw from the study, you may call our study line at <removed> and indicate your wish to withdraw.

COMPENSATION

We will compensate you $25 for completing each set of surveys (baseline, 6 months, 12 months) for your time and effort. You will receive $75 if you complete all three surveys. It may take up to 10 weeks for you to receive it either through an electronic fund transfer (EFT), a prepaid debit card, or gift card.

You do not have to receive these payments; however, if you want to receive them, we will need to collect your social security number to process your payments and to comply with Internal Revenue Service (IRS) guidelines. You may receive an IRS Form 1099.

CONFIDENTIALITY

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn that you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members.
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research).
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO).
- The VA committees that oversee research.
- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study.

Study Code and Link
If you agree to participate in our study, we will assign you a study code number. We will keep a master list that links study participants' names to code numbers separate from the study data in a secure VA database with restricted access.

Safekeeping and Storage
We will store all study data on secure VA password protected computers and/or locked files in secure offices that are accessible only to VA approved study research staff.

After Study Completion
In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

Once this study is completed, we will keep your data and code in a secure database in accordance with the VA records retention policy, which is currently set for a minimum of 6 years after the study has been completed. We may ask for your permission to enter your data into a research repository in the future. If this happens, we will contact you with more information. You do not need to participate in the repository to be in this research study.

QUESTIONS OR CONCERNS RELATED TO THE STUDY

If you have any questions about the study, you may contact *<removed>* if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research.

RESEARCH SUBJECT'S RIGHTS

If you have any questions about the study purpose, procedures, risks, discomforts, possible benefit, choices available to you, or your rights as a research subject, please discuss them with one of the researchers listed above prior to agreeing to participate in this research activity.

We very much appreciate your consideration
in participating in this study. Thank you!