Department of Veterans Affairs

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ORAL CONSENT SCRIPT

Study Title: COVID-19 in the Airborne Hazards and Open Burn Pit Registry
Principal Investigator: Michael J. Falvo, PhD
IRB #: 01521 _1584926-1
Version/Date: Version #1, January 2021

PURPOSE

You are invited to take part in a research study. The purpose of this study is to understand the short and long-term health effects of COVID-19 among Veterans who have participated in the Airborne Hazards and Open Burn Pit Registry and have received a positive diagnosis for the virus.

The COVID-19 pandemic is an ever-evolving event where the long-term health effects are still unknown. Among those who have been infected, some have few or mild symptoms that do not require hospitalization, but others have more severe symptoms requiring advanced medical care. In addition, the recovery – or lack of recovery – from COVID-19 symptoms also seems to vary between infected individuals as well. It is not currently known what is causing these differences across symptoms nor who may be at risk for long-term health impacts. Veterans may be at increased risk of long-term health impacts given their unique military exposure backgrounds.

PROCEDURES

If you decide to take part in this study, this is what will happen:

All session will take place either on the phone or via Veteran Video Connect (VVC).

You will be asked to confirm your identity before participating in study procedures.

Medical Record Review We will review your medical records to confirm information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Standardized Interview (approximately 60-90 minutes)
We will ask you a series of questions about your COVID-19 diagnosis, the symptoms you experienced and any treatments you received. We will also ask some general health questions, and questions about your home and environment.

Follow-up Interview (approximately 20-30 minutes)
We will follow-up 6 months after your initial interview, and every 6 months thereafter until it has been two years (24 months) since your COVID-19 diagnosis or re-diagnosis.

RISKS/DISCOMFORTS

All research has some degree of risk or discomfort. There are no significant risks to participating in this study.

Medical Record Review: We will review your medical records to confirm information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests. The risk is the same as loss of confidentiality below.

Questionnaires/Standardized Interview:
There are no physical risks, but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.

Breach of confidentiality:
As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality. We minimize these risks by utilizing a study ID which is a code (not associated with your personal information) and apply that code to all study related material. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication. The separate list is kept in a password protected file that is stored on a protected VA server with access granted only to the Principal Investigator and research study staff.

BENEFITS
There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us understand more about Veteran's health and COVID-19.

PAYMENT
You will receive $50 for your first interview and $25 for follow-up interviews. Payment will be in the form of a mailed check following study appointment.

VOLUNTARY PARTICIPATION
You do not have to agree to be in this study, and you may change your mind at any time.

- Call the principal investigator, Dr. Michael Falvo, at 201-414-8270 if you have questions or complaints about being in this study.
- If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the local IRB at 973-676-1000 x 2778.

PERMISSION TO PROCEED
Is it ok to proceed with the interview described previously?