

COVID-19 Observational Research Collaboratory -  
Long-Term Outcomes (LTO) Study

NCT05394025

July 17, 2022

**Department of Veterans Affairs  
Research Information Sheet**

**VAAHS Research IRB**  
Approved 07/17/2022




**Title of Study:** Measuring the causal effect of COVID-19 on Veterans who survive

**Principal Investigator:**



**VAMC:** VA Ann Arbor  
Healthcare System

You may be asked to participate in a research study conducted by  at the VA Ann Arbor Healthcare System. We are conducting a study to understand the long-term effects of COVID-19 on Veterans. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

**WHY IS THIS STUDY BEING DONE?**

We are conducting a research study to understand the long-term effects of COVID-19 infection among Veterans.

**WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?**

If you agree to participate, you will be asked to complete a survey over the phone about every 6 months for 36 months (up to 4 surveys total). This survey should take about 30-minutes to complete. In each survey, we will ask you questions about your physical and mental health and wellbeing, financial impact of the last few years, mobility, and healthcare use. The survey also includes a depression symptom questionnaire. We will recruit both Veterans who had COVID-19 and those that have not. You may also opt to complete a mailed paper survey instead of a phone survey.

You do not have to answer all of the questions in this survey. If a question makes you feel uncomfortable, you can just skip it and go to the next question.

You can decide to leave the study at any time and it will not be held against you. If you decide to withdraw, we will keep the data we have already collected from you and we will not contact you any further.

You will not receive any aggregate or individual study results that may come from your participation in this study.

In order to build a complete, accurate picture of how COVID-19 infection affects Veterans—whether or not they themselves had COVID—we are seeking your permission to link your survey responses with your VA Electronic Medical Record only for the purposes of this research.

Future use of your data: By enrolling in this study, we will also ask if you agree to the storage, secure sharing, and use of your research data for future use in research studies related to Veterans' health conditions. Researchers that access your data for future research use may be national or international and affiliated or unaffiliated with the VA. Your data will *only* be used for research purposes. An institutional review board (IRB) will review all future research proposals and help researchers determine if results should be shared with you. Future studies will be reviewed and approved by an IRB and other oversight committees before any research begins.

Additionally, by agreeing to participate in this study, you are also agreeing to be contacted for future studies. You always have the right to say "no" to any future research.

## **WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY (BENEFITS)?**

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers' understanding of the long-term effects of COVID-19 on Veterans.

## **WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY (RISKS)?**

A potential risk is psychological distress that may result from answering questions related to COVID-19.

Another risk we can foresee is the unlikely event in which confidentiality is breached. While we aim to keep our surveys as brief as possible, another risk may be the inconvenience of the survey commitment to your work or personal obligations.

We have taken multiple measures to protect you and to reduce these risks.

## **DO YOU HAVE TO TAKE PART IN THE STUDY?**

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

## **WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?**

The information collected for this study will be kept confidential. To minimize the risk of a breach of confidentiality, we will perform the following steps:

- First, each Veteran will be assigned a unique study ID.
- We will then create a password protected electronic tracking file that maps the study participant's identifying information to the study ID. No identifying information will be placed on surveys. Any identifiers we collect will be kept in password protected files for the duration of the project and will then be destroyed according to VHA Records Control Schedule 10-1 (RCS 10-1).
- Electronic data will be maintained behind a secure firewall maintained by the Ann Arbor study team. All identifiable data will be kept behind the firewall, with access only available to key study team members.
- All resulting research data will be presented in aggregate only.
- Study staff are required to complete annual training on privacy and Health Insurance Portability and Accountability Act (HIPAA), as well as biannual training on human subjects protection. Access to participant data, both paper and electronic, will be given to VA project staff only and on an "as-needed" basis.
- There are no treatments, procedures, or interventions as part of this study. Any complaints/concerns expressed to the study staff by participants, providers, or anyone else affected by this study will be immediately reported to the Principal Investigator and IRB, as will any unexpected events.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

## **WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?**

Participants will be mailed a \$10 gift card for completing each survey, totaling \$40 for completing all assigned surveys.

## WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions, comments or concerns about the research, please contact:

- Principal Investigator: [REDACTED]
- Project Manager: [REDACTED]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA IRB Coordinator at [REDACTED].