



Information Sheet and Authorization

IRB#21302

TITLE: Multi-center registry of COVID-19 patients presenting to emergency departments in the United States

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CO-INVESTIGATORS: Esther Choo 503-494-1440

**WHO IS PAYING FOR THE STUDY?: OHSU
Oregon Clinical and Translational Research Institute
(OCTRI)
National Heart, Lung, and Blood Institution (NHLBI)**

WHY IS THIS STUDY BEING DONE?:

You have been invited to be in this research study because you have been evaluated for symptoms potentially consistent with viral illness such as COVID-19. The purpose of this study is to learn more about the clinical course and outcomes of similar patients, and to help guide health systems and emergency departments during the current pandemic.

We are also asking you to provide information for a data bank, also called a repository. These data will not have any information that could identify you. They will be stored indefinitely without identifiers and may be shared with other researchers for research related to COVID-19.

WHAT PROCEDURES ARE INVOLVED IN THIS STUDY?:

You will receive an invitation by cell phone or email to answer 5 questions about your symptoms, any testing you received, and if you have needed hospitalization. These questions should take less than 1 minute to complete and will be sent weekly for 30 days. We may send you a brief survey after 30 days to assess how you are doing in the future. We will also use information from your medical records.

WHAT RISKS AND BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:

You may receive some benefit from this study, as we are tracking symptom severity and based on that you may receive guidance about returning to care. You will also be directed to disease prevention information from the Oregon Health Authority. However, by serving as a subject, you will also help us learn how to benefit other patients during the current COVID pandemic and in the future. Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?:

This study is voluntary. You may choose not to be in this study.

WHO WILL SEE MY PERSONAL INFORMATION?:

We will take steps to keep your personal information confidential, although we cannot guarantee total privacy. We will keep your information confidential by using a generic study ID, rather than with your name or other personal information, and on an encrypted computer. We will remove your name and other identifying information from the data as soon as you are done with the surveys. When we share your information with other researchers, it will not have any information that could identify you.

We may have to release the study information to oversight organizations for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) at OHSU, or Office of Human Research Protection (an agency that oversee research).

If your information goes outside of OHSU, it might not be protected under federal law from being used or

further shared. By agreeing to be in this study, you are giving permission for us to use and disclose your health information as described above. If you decide you do not want us to use your health information, you can request this by contacting us at:

Craig Newgard, MD MPH or Esther Choo, MD MPH
newgardc@ohsu.edu or chooe@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

You do not have to allow us to use your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care at OHSU or insurance coverage.

WHERE CAN I GET MORE INFORMATION?:

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Dr. Craig Newgard (503-494-1668) or Dr. Esther Choo (503-494-1440).

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time.

HOW DO I TELL YOU IF I WANT TO TAKE PART IN THIS STUDY?

Please indicate whether you provide your consent to participate in this study using the check boxes below:

Yes, I would like to participate in the study. No, I would not like to participate in the study.