

Important Information about Research Participation During COVID-19

In an effort to more fully educate and prepare those who may be considering joining a study at this time or those who are currently enrolled in a study, we aim to provide important information about COVID-19, the virus responsible for the current global pandemic, and to review ways in which your study participation might change because of risks related thereto. To ensure appropriate safety precautions when conducting in-person study procedures, all relevant CDC, State, Local, and TU guidance shall apply, including [Tigers Care: Health Guidelines](#), [Return to TU: Guidance and Protocols](#), and the [Community Responsibility Commitment](#).

How is COVID-19 spread? COVID-19 is a respiratory virus spread mainly by respiratory droplets, generally from person-to-person and between people who are in close contact with one another. There is some indication that it is possible that COVID-19 may be spread by people who are not showing symptoms. It is also possible that a person can get COVID-19 by touching a surface or object that has the virus on it, then touching their mouth, nose or eyes.

Can COVID-19 be prevented? Current ways to minimize the risk of exposure to COVID-19 include wearing a mask in public settings and when around people who don't live in your household, especially when other social or physical distancing measures are difficult to maintain. Social or physical distancing means to keep a safe space between yourself and other people who are not from your household, and includes staying at least six feet apart in both indoor and outdoor spaces, and, in conjunction with wearing masks and avoiding touching your face with unwashed hands, and frequently washing your hands with soap and water for at least twenty seconds, should help reduce the spread of COVID-19. It is important to understand that as participation in a research study may include increased travel outside of your home and increased exposure to others within a clinical care environment or research site it may increase your exposure to COVID-19.

What are the risks and symptoms related to COVID-19? People with COVID-19 have had a wide range of symptoms reported from mild symptoms to severe illness. For most people, the new coronavirus causes only mild or moderate symptoms (fever, cough, loss of taste or smell). However, for some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia. See also the Centers for Disease Control and Prevention (the CDC) website for [additional information](#) on those people who may have an increased risk of contracting the virus.

Are there treatments available? The CDC has authorized and recommended use of several COVID-19 vaccines. The federal government is working toward making vaccines widely available for everyone at no cost. The CDC is providing recommendations to federal, state, and local governments about who should be vaccinated first, but each state has its own plan for deciding which groups of people will be vaccinated first. You can contact your [state health department](#) for more information on its plan for COVID-19 vaccination.

How could your participation in this research change as a result of COVID-19? There are several ways we try to minimize your risk. If possible, we limit the number of times you have to come to a clinical care or research site. We ask every research participant if they have the symptoms of COVID-19 or have been in close contact with any cases. We reduce the time you are exposed to other people as much as possible. If you are suspected to be positive for COVID-19, there may be last minute changes to how research procedures are performed [such as a change from an in-person visit to a telephone call] or cancellations of research tests or procedures to ensure your safety.

The information related to risks of COVID-19 changes every day. We are monitoring these risks and deciding how these risks should change our research. If you have questions about COVID-19 and your participation in research, please consult with the study team.

PI to identify specific risks to the research subject associated with this research (e.g. no masks to be worn, physical contact, etc):

1. _____
2. _____
3. _____